

EU-U.S. High Level Working Group on Jobs and Growth Response to Consultation by EuropaBio and BIO

Introduction

This submission is jointly put forward by EuropaBio and the Biotechnology Industry Organization (BIO) in response to the request for comments regarding regulatory cooperation activities that would help eliminate or reduce barriers to trade. Both EuropaBio and BIO welcome and support the continued coordination between the U.S. and EU on trade issues. Persistent and scientifically unjustified barriers to products derived from agricultural biotechnology continue to inhibit innovation and growth of companies with limited resources, unnecessarily restrict trade, and increase the risk of trade disruption of key agricultural commodities. It is of mutual interest that trade of products derived from agricultural biotechnology be normalized.

In 2006, a World Trade Organization (WTO) dispute panel found that the EU's de facto moratorium on agricultural biotechnology product approvals and several Member States' bans on cultivation were inconsistent with their commitments under the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. This dispute remains unresolved, and the potential for resolution is increasingly uncertain.

EuropaBio is the voice of the European biotech industry. Membership includes a wide range of corporate members and industry associations involved in biotechnology throughout Europe. EuropaBio has 56 corporate and 14 associate members and BIO Regions and 19 national biotechnology associations - representing some 1800 small and medium sized enterprises across Europe. EuropaBio's primary focus is the European Union but we also represent our members in transatlantic and worldwide discussions. EuropaBio represents all 9 seed and breeding companies, including the producers of all commercial GM varieties in the EU approval system or of those that have already been approved. **Contact:** Carel du Marchie Sarvaas, Director - Green Biotechnology Europe, EuropaBio, Tel: +32-2-739 11 85, c.dmsarvaas@europabio.org www.europabio.org

The **Biotechnology Industry Organization (BIO)** is the world's largest biotechnology trade association. BIO provides advocacy, business development, and communications services for more than 1,100 members worldwide. Its mission is to be the champion of biotechnology and the advocate for its member organizations - both large and small. BIO members are involved in research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals, as well as state and regional biotechnology associations, service providers to the industry, and academic centers. **Contact:** Cathleen Enright, PhD, Executive Vice President, Food & Agriculture, Biotechnology Industry Organization (BIO), Tel: +1 202-962-6644/9200, cenright@bio.org, www.bio.org

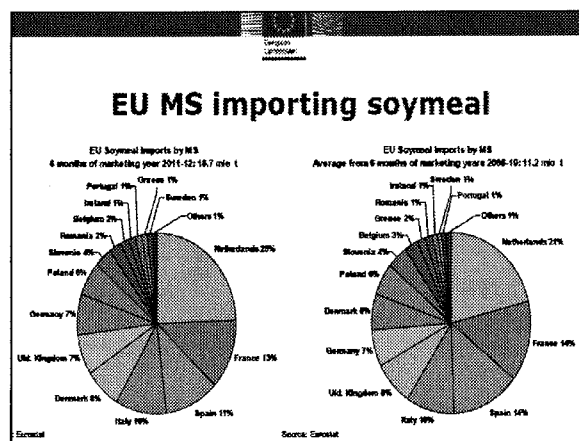
This submission has five sections:

1. Growing trade of agricultural commodities with genetically modified (GM) origin
2. Asynchronous global GM crops approval systems
3. Trade impacts
4. Steps that EU and the U.S. should consider
5. Conclusions

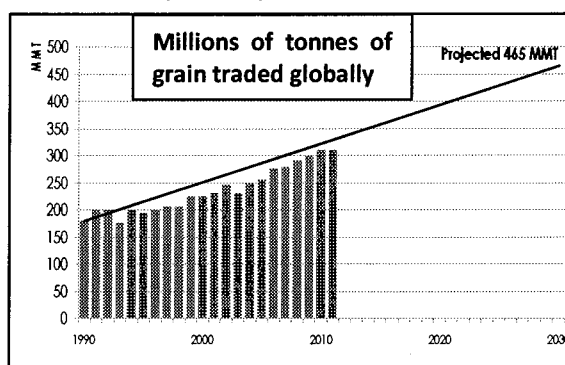
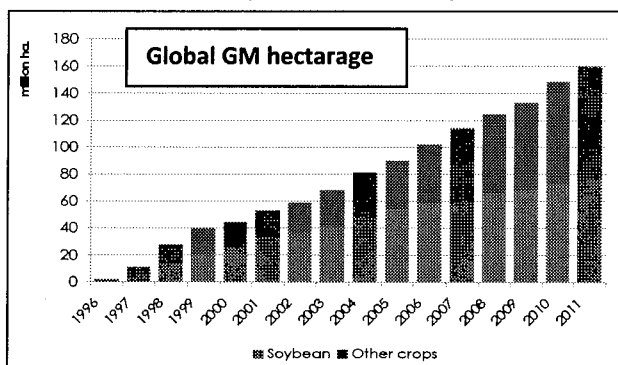
1. Growing trade of agricultural commodities with genetically modified (GM) origin

The EU is the biggest net importer of agricultural commodities (unprocessed products that are mainly traded in bulk, such as grains and oilseeds). The EU is also by far the biggest importer of agricultural products in general, which include intermediate and final products. Agricultural imports reached €98 billion in 2011¹. The biggest exporters are North and South American countries, where modern biotechnology crops are widely grown and have contributed to higher productivity. European import dependency is particularly high for soya where EU domestic production covers only 7% of demand.

The EU's livestock sector comprises approximately 40% of total EU agricultural production. Livestock farmers depend on the availability of quality feed at good prices. EU livestock feed contains ingredients made from GM crops. Compound feed consumption represents ca. 150 million tons². Soy meal accounts for 55% of protein-rich animal feed. Roughly half of the approximately 40 million tons of raw soy products imported into the EU per year is used in animal feed. Almost two thirds of EU maize production is used in animal feed, with some GM maize being grown in EU countries.



There is a rapid increase of GM cultivation in the U.S. and other countries that export to the EU. In 2011, 16.7 million farmers planted 160 million hectares of biotech crops in 29 countries, up 8% from 2010. Soy, harvested in the three main countries from which the EU imports, is mostly GM: in the U.S., Brazil and Argentina, GM adoption rates for soy stand at 92%, 83% and 99% respectively, and continue to increase.



There is rapid growth of internationally traded commodities, most notably soy and maize products, most of which contain more GM products. The EU imports upwards of 30 million tons annually - equivalent to 60kg per EU citizen per year (500 million). Asian nations demand for soy and maize products is increasing even faster than EU demand, which increases the competition for supply.

¹ EU Commission, MAP, May 2012 http://ec.europa.eu/agriculture/publi/map/index_en.htm

² FEAC, <http://www.fefac.eu/file.pdf?FileID=34736>

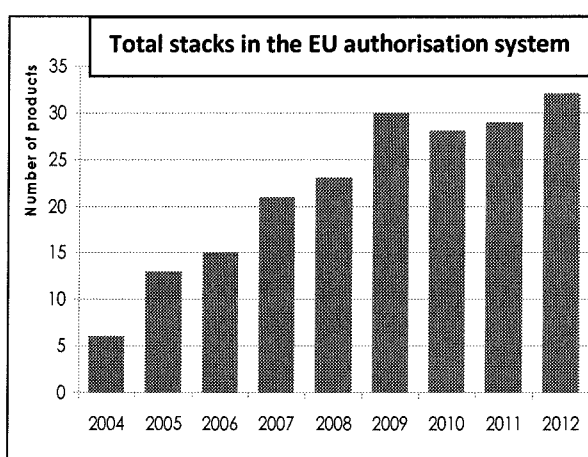
2. Asynchronous global GM crops approval

The number of GM product approval requests in the EU is increasing, and more products will enter the EU system. In 2007, 51 products were in the system; in 2012, it is 75. At current rates, this is projected to rise beyond 100 products in the system by 2015. Currently, twice as many products enter the EU approval system than exit it on average each year.

There is a growing gap between approval timelines in major markets. Global approval timelines are increasingly asynchronous. The U.S. Government and most other North and South American nations operate faster approvals systems than the EU, and they have decided to accelerate further. While the EU takes close to 3.5 years on average for an import approval, the U.S. is aiming at 1.5 years (Brazil currently takes just over 2 years and Argentina introduced measures in 2011 to cut approval times by 50% (currently about 1.5 years for single events). The EU spends almost a third of the total time in the approval process on administrative processing, rather than on safety assessments. The burgeoning backlog of GM products awaiting approval/processing represents a major barrier to trade.

In the EU there is a failure to act as prescribed by EU law. After receipt of an EFSA Positive Opinion for products for import, the Commission often fails to respect the timeline set in Article 7 of Regulation 1829/2003 about GM products for import and food/feed use. This states that after EFSA has issued a Positive Opinion on a GM product, the European Commission must act: *“Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committeea draft of the decision to be taken in respect of the application....”* Rarely has this deadline been met. Currently 18 products have a positive opinion from EFSA and are waiting for Commission action – some already for many months. The actions, or lack thereof, of the Commission and its motivations lack transparency and predictability and are the main cause for late, slow or no decisions. This has allowed the creation of a bureaucratic limbo, which was identified by the Commission’s evaluation report about 2001/18 which states that *“...the process has been able to stall without any legal implication”* (page 51).

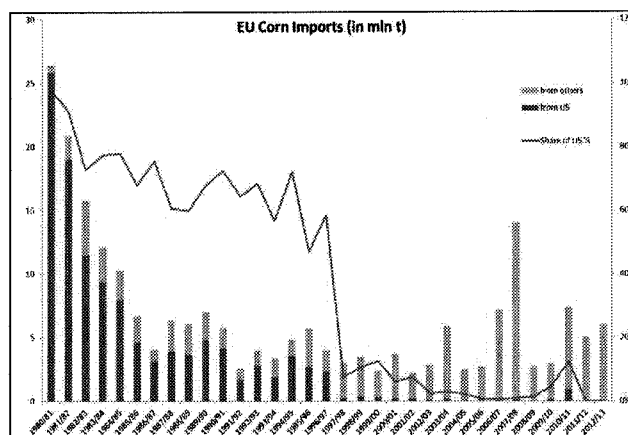
More complex stacked products will need to be approved. Most GMOs entering the market today are stacked events, in which two or more GM traits are combined by means of conventional crossing. Therefore, the number of stacks to be approved in the EU is growing. Different handling of stacks by different jurisdictions is a cause for concern. With the exception of the EU, most governments do not assess stacks separately as new products. When a stacked event is approved in most markets, any sub combination of that event with other approved singles is also approved (or is approved thereafter with a rapid procedure). The EU has a policy of only starting the risk assessment of a stacked product after the risk assessment of the single events composing that stack is completed. The data requirements for stacked products are also higher in the EU. These three factors slow down EU approvals of stacks, often by more than a year compared to approvals of single events.



Source: EuropaBio

3. Trade impacts

The chart shows the decline of U.S. to EU corn exports. The large drop in the middle of the chart in 1997/1998 coincides with the introduction of GM in the U.S. market. Trade has never picked up again to the same levels. Similar trends can be seen in other commodities like rice, with the US share in EU imports of husked rice (non-Basmati) dropping from 44% to 4% from one season to the next following an LLP incident in 2006.



Source: Coceral 2012

100% purity is impossible in the production of food, feed and seed. Agricultural commodities inevitably become inter-mixed to a small extent. This mixing results in adventitious presence (technically unavoidable presence) of impurities without affecting quality or saleability of the crop. EU regulations usually reflect the inevitability of admixtures – except when it comes to GM crops. The zero-tolerance policy in the EU implies that imports containing minute traces of GM varieties that are as yet unapproved in the EU are not allowed into the EU. It has become increasingly difficult over the last years to import commodity grains from countries that widely use GM varieties.

It is commonly the case that a GM trait is already authorized for commercial use or sale in one or more exporting countries, but not or not yet covered by an authorization in the country of import. Due to asynchronous approval, shipments that contain traces of GM crops can be rejected at the port of entry, or diverted to other continents (see case studies overleaf). The likelihood of presence of not yet EU-authorized GMOs in imports is increasing continuously. In addition, the ability to manage this issue is more challenging. *“The logistical capacity of segregation in the main exporting countries to the EU... is not able to cope with the requirement of segregating GM material that is EU authorised from unauthorised”*, according to report published by the Commission³. This is less a problem in the U.S. because GM products are approved faster and earlier in the U.S. than in the EU.

The EU has adopted a 0.1% tolerance threshold for testing, which applies to feed only. This entered into force in 2011. This so-called ‘technical solution’ does not replace the EU’s zero-tolerance policy, but it simply addresses the uncertainties related to methods of sampling and analysis. It is unlikely that a 0.1% tolerance threshold will be able to cope with quantities and varieties of GM products being planted around the world.

Trade disruptions have major consequences. First, there is the increased cost of raw materials to the EU. Cost increases have run into the billions of Euros. This negatively impacts EU farmers, livestock breeders, commodity importers and their users, food companies. If there is doubt, grain traders will avert the risk that their ships will be denied from unloading in the EU and reroute to locations where they will not encounter problems and where they are welcomed. National and EU authorities are responsible for

³ Study on the Implications of Asynchronous GMO Approvals, executed on behalf of DG AGRI, December 2010: http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/summary_en.pdf

managing such preventable high profile incidents. These incidents decrease public trust in both the capacity of authorities and in the technology. They may lead to recalls of consumer products, as happened with the rice incidents in 2006.

Blockage of soymeal from the EU's main suppliers as a result of traces of non-authorized GMOs would result in a soybean price increase of over 200% and could see farm profits drop by around € 3 billion for the beef sector, € 1.2bn for the dairy sector and € 1bn for the pig meat sector. Despite possible gains for domestic feed producers, the overall cost to the economy of such disruptions could total € 9.6 billion, according to a recent report published by the EU Commission.⁴

Case Study 1: Trade Disruption: Unauthorized GM maize in imports. In 2006, a new GM maize product was introduced in the U.S. It entered the EU authorization system in 2005. About 1% of total U.S. maize area was planted with this type of maize. A comprehensive plan was implemented among farmers, traders and authorities to segregate product flows in transport, storage and in the fields. The EU authorities were fully informed of the plan. Despite the unprecedented and extensive measures, 54.5% of all tested samples on U.S. barges were positive, and shipments entering Europe were found to contain the maize. The cost of the resulting trade blockages was tens of millions of Euros. The maize was finally approved in the EU in September 2007.

Case Study 2: Trade Disruption: Maize dust in soy shipments. In 2009, bulk shipments of soy from the U.S. were turned away from European ports because they contained detectable traces of GM maize not yet approved in the EU and left in the ships from previous shipments. Three unauthorized GM maize products were found. Hundreds of thousands of tons of GM soy were refused entry. Grain traders, who had their ships stuck in EU ports or had to re-route them at high cost, decided to avert risk and stopped all imports of soy products from the U.S. Soybean prices jumped. After the products were authorized, soybean prices returned to normal. The extra cost of feed imports was estimated to be between euro 3.5 -5.5 billion.

⁴ Study on the Implications of Asynchronous GMO Approvals, executed on behalf of DG AGRI, December 2010: http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/summary_en.pdf

4. Steps that the EU and U.S. should consider

To find a long-term solution to current barriers to agricultural biotechnology, the U.S. and EU must consider a systematic approach to normalize trade. The WTO SPS agreement calls on Members to initiate negotiations. Unless the outcome of these discussions becomes more productive, the unacceptable status quo is likely to be perpetuated.

The starting point is a more efficient EU authorization system with data requirements and approval timeframes more in line with the U.S. and other comparable systems. Requests for additional, unnecessary data and information are particularly burdensome to smaller, innovative developers with limited resources and staffs. The European Commission should first and foremost implement EU legislation - it should put forward all products that have received an EFSA Positive Opinion for voting within the legally foreseen timeline of 3 months.

The chart below sets out many specific efficiency recommendations, most of which are explained in detail in three reports - two funded by the Commission: http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm. Another by EuropaBio at: <http://www.europabio.org/agricultural/positions/approvals-gmos-european-union>

Process efficiencies in the European Commission (predictability and timing) <ul style="list-style-type: none"> Legally prescribed timelines should be respected Scfcah meetings should not be cancelled - votes should take place at the first available meeting A specific action plan to address the backlog should be initiated. This will require more time and political weight to be devoted to processing authorizations efficiently.
Political risk assessment <ul style="list-style-type: none"> Maintain EFSA's autonomy: new requirements to be added by EC only if EFSA deems necessary
Efficiency improvements for EFSA <ul style="list-style-type: none"> A transparent implementation of a work plan for each application Parallel and auditable risk assessment (by different working groups and by the different MS) A more structured process for information exchange between applicants and the EFSA
EFSA guidance: re-interpretation/ retroactivity <ul style="list-style-type: none"> Avoid retroactive application of requirements. Any change should be clearly communicated EFSA should set clear endpoints and a rationale for certain case-by-case recommendations Need for clear date of entry into effect; need for a transition period
Stacks, scope, stand alone, renewals <ul style="list-style-type: none"> Stacks: Applications to be reviewed in parallel with their singles. Failing the above preferred option, if separate applications: reduce stack application to a simplified procedure or a notification Scope: For products with EFSA opinion, a new application can be submitted following a mutual agreement between the applicant and the Commission - simplified procedure Stand alone: EFSA/applicants should agree a format to centralize/ update data packages for singles. Renewals: For renewals, a simplified assessment should be performed that takes into account prior assessments. It would be logical that a renewal is also given for a single when a stack is approved.
Escalation of data requirements <ul style="list-style-type: none"> Global harmonization of principles and study requirements (Codex) Pre-consultation meetings with applicants before new requirements
Late and questionable mandates to EFSA <ul style="list-style-type: none"> The 30 day window for comments by general public should be respected Specific panel to deal with the validity of the issues raised should be instituted

The “technical solution” should be extended to include food. But, it should be clear that this remains a tool under the current “zero tolerance” policy. In order to take account of the dynamics of the international adoption of GMOs in agriculture, it should be recognized that such a “zero tolerance” policy is ultimately untenable, given the global trading trends. Zero tolerance of products assessed by multiple food safety agencies all operating basically the same approval approach around the world is unnecessary.

A LLP policy for EU unauthorized GM products in feed, food and seed is needed. The policy should consider practical approaches to: unauthorized products, discontinued events, off-license products and products not submitted for approval in the EU. The EU should contribute to ongoing international efforts to coordinate LLP policies worldwide,⁵ and also consider the option of mutual recognition of safety assessment data. The establishment of LLP rules does not compensate for the serious asynchronicity in approval timing between production countries and the EU.

Another option that deserves more attention is the possibility of mutual recognition of approvals with third countries. But, as progress on both of the before mentioned options is very slow in the EU, there is an urgent need for workable thresholds for feed, food and seeds. As many commodities can easily find their way both into food and feed supply chain, and segregation between commodities for feed and those for food is not practically possible, an extension of the existing ‘technical solution’ to cover food is needed as a matter of urgency.

Adventitious presence of GM seeds can occur in non-GM seed – in just the same way as off-types have long been found in conventional varieties. Clearly, the widespread cultivation of GM crops in many non-European countries also increases the possibility of adventitious presence of these GMOs in the non-GM seed produced in these countries for export. Expecting an adventitious presence standard of “absolute zero” is neither realistic nor possible.

The European Commission has indicated that it wants companies to reduce the use of Anti-biotic Resistance Markers (ARMGs). In 2012 the EU notified the WTO of the Implementing Regulation for authorizations of GM food and feed, which ‘recommends’ applicants to develop products without ARMs. Any approach to limit ARMGs must be science-based and must respect product lifecycles. The implication of the EU’s policy to regulating stacked events is that applicants are required to submit stacks that may contain singles that use ARMGs. The inclusion of a de facto limit on ARMGs could have seriously negative consequences on trade.

5. Conclusions

International trade increases everyone’s livelihood. Trade allows each country to specialize in the activities according to comparative advantage. By trading with others, consumers and producers can buy a greater variety of goods or services. In this document, BIO and EuropaBio have presented concrete suggestions on how to make regulatory regimes on agricultural biotechnology more compatible across the Atlantic and therefore facilitate the international trade flow of key commodities to the EU.

The biotechnology industry is willing to assist and participate in any projects related to facilitating more positive and productive agricultural trade relationships. We would appreciate and welcome the opportunity to meet and engage in a discussion with authorities on both sides of the Atlantic on these

⁵ International declaration on LLP signed by 13 governments in September 2012:
http://64.76.123.202/site/agregado_de_valor/biotecnologia/archivos/DECLARACION06sep2012.pdf

matters, and offer our support and assistance as the EU and the U.S. government look to enhance their trade relationship.

**Confindustria Federorafi**

Federazione Nazionale Orafi Argentieri

Gioiellieri Fabbricanti

Gold Jewellery – Silverware and Jewellery Sectors
Reciprocity between USA and EU customs regulations
as regards Outward Processing Trade

No trade reciprocity

With particular reference to the United States market, the most important jewellery market worldwide, the European gold jewellery sector operates in a less competitive manner as European products are penalized in terms of customs duties compared to items produced by other manufacturing countries and compared to the tariffs applied by the EC on United States products.

UE has experienced difficulties in accessing the US market because custom duties are applied not only on the value added on the processed product, but also on the value of the raw material. This does not constitute a barrier for accessing the market, but rather the impact produced by the American legislation, which regulates outward processing trade in a different manner to the European legislation, hindering the use of the USA outward processing trade scheme for the working of precious metals (gold, silver, platinum ...) in third countries.

As it is customary for the sector's jewellery manufacturers to import raw materials from United States clients and to re-export finished jewellery items, if these operators were to adopt outward processing trade operations, this could reduce the impact of the higher customs duties, thus avoiding – as occurs at present – the customs duties being calculated not only on the value added part of the processing, but also on the raw material, which clearly constitutes the prevailing part of the product value (accounting for about 90%).

However, despite the fact that the current EC customs regulations can be considered as the basis for developing this kind of operation, an outward processing trade regime, which could be applied in general terms, is missing in the United States regulations, thus excluding gold jewellery operators from the potential benefit of the same. *

Besides the alternative solutions suggested to solve the problem of more equitable competition within sector, that is an overall reduction in United States customs duties or defining a sectorial free trade agreement within the WTO framework, we propose evaluating the possibility of supporting, within the existing structures designated to conduct EU-USA bilateral negotiations, a proposal for harmonizing the United States and European Community customs regulations, with the aim of attaining reciprocity, which would foster the above-mentioned outward processing trade operations.

* i.e.: Part 10 (Articles conditionally free, subject to a reduced rate) of the Chapter 19 (Custom Duties) of the US Code of Federal Regulations. **Art. 10.9 (Articles exported for processing):**

CONFINDUSTRIA FEDERORAFI

“(a) Except as otherwise provided for in this section, the following documents shall be filed in connection with the entry of articles which are returned after having been exported for further processing and which are claimed to be subject to duty only on the value of the processing performed abroad under subheading 9802.00.60, Harmonized Tariff Schedule of the United States (HTSUS)”.

9802.00.60 of the HTSUS subchapter II (Articles exported and returned, advanced or improved abroad), it says that *“Any article of metal (as defined in U.S. note 3(e) of this subchapter) manufactured in the United States or subjected to a process of manufacture in the United States, if exported for further processing, and if the exported article as processed outside the United States, or the article which results from the processing outside the United States, is returned to the United States for further processing”* where metal is defined as: *“(e) For purposes of subheading 9802.00.60, the term "metal" covers (1) the base metals enumerated in note 3 to section XV; (2) arsenic, barium, boron, calcium, mercury, selenium, silicon, strontium, tellurium, thorium, uranium and the rare-earth elements; and (3) alloys of any of the foregoing”.*

The metals included in the note 3 of section XV are: iron and steel, copper, nickel, aluminium, lead, zinc, tin, tungsten (wolfram), molybdenum, tantalum, magnesium, cobalt, bismuth, cadmium, titanium, zirconium, antimony, manganese, beryllium, chromium, germanium, vanadium, gallium, hafnium, indium, niobium (columbium), rhenium and thallium.

(Gold, silver and other precious metals do not seem to be contemplated).



THE GLOBAL VOICE
OF MUSIC
PUBLISHING

Brussels, 31 October 2012

Daniel Calleja Crespo, Director General, DG for Enterprise and Industry
Jean-Luc Demarty, Director General, DG for Trade

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

Sirs,

I am writing to you on behalf of ICMP, the International Confederation of Music Publishers and on behalf our member organisation, the National Music Publishers Association in the US (NMPA US), in relation to the matter - EU and US call for input on regulatory issues for a possible future trade agreement.

ICMP is the world trade association representing the interests of the music publishing community internationally. We speak out on behalf of music publishers across the world to safeguard their creative and economic interests and to help them meet new and emerging challenges in the music business. Collectively, our members represent hundreds of thousands of songwriters, composers and lyricists from every corner of the globe. Constituent members of ICMP are music publishers' associations from Europe, Middle East, North and South America, Africa and Asia-Pacific. Included are the leading independent multinational and international companies and regional and national music publishers, mainly SMEs, throughout the world.

NMPA US is a music publishing trade association with over 2500 members whose mission is to protect, promote, and advance the interests of music's creators. The NMPA is the voice of both small and large music publishers, the leading advocate for publishers and their songwriter partners in the nation's capital and in every area where publishers do business. The goal of NMPA is to protect its members' property rights on the legislative, litigation, and regulatory fronts.

ICMP members represent publishers who are engaged in numerous commercial transactions between the EU and the US, and as such our particular interest in EU and US trade discussions is Intellectual Property Laws and the approaches to their enforcement. We welcome the willingness of the European Commission and the US Government to promote greater regulatory compatibility generally. ICMP believes, however, that in order to promote this compatibility, it is essential to first achieve a greater degree of harmonisation in the EU and this submission therefore will look primarily at areas of difficulty within the Union.

Within the EU, the main problem faced by rightsholders is legal uncertainty. European and non-European stakeholders are for example faced with different **regulatory offices**. There is no single

37 Square de Meeus, 1000 Brussels
P.O. Box 80, Sonnhalde 5, 8602 Wangen/ZH, Switzerland

www.icmp-ciern.org



THE GLOBAL VOICE
OF MUSIC
PUBLISHING

point of reference when rightsholders encounter a problem. Each Member State has its own office dealing with Intellectual Property Rights (IPR) issues, and they apply EU IPR laws as implemented by the Member State. While it is welcomed that EU law allows Member States flexibility, nevertheless when it comes to the specifics of implementing EU IPR legislation, a level playing field and a consistent approach to implementing and enforcing the laws, and providing remedies in cases of infringement, is very much needed. This is not only the case for EU companies and individuals but also for non-EU parties as they face many different laws and regimes when operating within the EU.

In this regard, ICMP commends the fact that the OHIM (European Office for Harmonisation of the Internal Market) has now been given responsibility for a wide range of tasks relating to research, training, communication, and the development of advanced IT support tools and the enforcement of all types of IPRs. We also welcome the work of the European Observatory IPRs on Infringements of Intellectual Property Rights. Both bodies will greatly contribute to the development of a more coordinated approach to tackling IPR infringements and to the introduction of more efficient enforcement measures.

As an organisation representing rightsholders, the **relevant regulatory and/or statutory provisions** for ICMP in the EU are: EU Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society; EU Directive 2004/48/EC on the enforcement of IPRs; EU Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce); and the Proposal for EU Directive on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online uses in the internal market.

We are pleased with the current EU regulatory framework on IPRs; we believe there are comprehensive pieces of legislation that provide rightsholders with a satisfactory level of protection. Yet, we see that these laws also include a number of shortcomings as a result of the flexibility that EU Member States have to implement the laws in whatever way they deem most efficient (some Member States adopt more stringent rules than others), and there are a number of **regulatory differences** that should be addressed.

One example of this lack of harmonisation is Article 5 of the EU Directive 2001/29/EC on exceptions and limitations to copyright. First of all, there is no *numerus clausus* of the different cases, and Member States can add to the list as they see fit. Secondly, the Directive only outlines the principle and leaves the implementation to the Member States in accordance with the principle of subsidiarity. One of the consequences of this practice is the situation we now have with regard to private copying levies and the related disparities in the different Member States.

37 Square de Meeus, 1000 Brussels
P.O. Box 80, Sonnhalde 5, 8602 Wangen/ZH, Switzerland

www.icmp-ciem.org



THE GLOBAL VOICE
OF MUSIC
PUBLISHING

Another example is the EU Directive 2004/48/EC, in relation to which Member States interpret enforcement measures differently. ICMP's main concerns relate to the different interpretations of the provisions on damages, injunctions and the right of information.

We would also like to mention our concern about the "Bars and Grills exception" that is still a part of US legislation, and according to which over 70% of the bars and restaurants in the US are exempted from paying royalties for broadcasting musical and audiovisual works on their premises. Despite the WTO ruling in 2000 which found that this US law is contrary to TRIPS, the law has remained unchanged. It is true that European authors and composers received compensation of sorts at the time of the settlement, but since 2004 European rightsholders have not received any further remuneration.

Possible solutions for bridging these differences are the following:

In relation to EU Directive 2001/29/EC, ICMP welcomes the discussions with the High Level Mediator Antonio Vitorino. A possible solution to the problem of disparities in the methodology for setting tariffs is that, for example, rates should be balanced and open to regular revision reflecting technological and economic developments as well as changes in consumer behaviour in the Member States. Rates should therefore be set according to the average estimated level of use and storage capacity of recordable equipment and media.

In relation to the EU Directive 2004/48/EC, the Commission should seek to remedy identified problems concerning the different interpretations of the Directive's provisions by proposing specific improvements/clarifications and launching infringement proceedings against Member States whose national laws are inconsistent with the terms of the Directive.

In relation to the EU Directive 2000/31/EC, the EU should recognise the models for fighting against internet theft that are emerging and working in some Member States such as Sweden and France, and in the US, and should require the introduction of equally effective systems elsewhere across the EU. This could be done via legislative initiatives mandating ISP cooperation, requiring warning and/or educational messages to be sent to infringing subscribers' accounts and obligating Member States to enact effective deterrent mechanisms against recidivists. In our view, the EU should adopt clear provisions that encourage and require ISPs to cooperate to reduce online infringement so that all parties – rights owners, digital service providers and consumers – can benefit from the growth of a licensed digital market. Furthermore, the process of notifying ISPs of illegal content could be facilitated and harmonised through a standardised procedure that is easily accessible, simple to complete electronically and not conditional on fulfilling other conditions.

Concerning the US Bars and Grills exception, we call upon the US Government to make US legislation in this regard compliant with the TRIPS Agreement.

37 Square de Meeus, 1000 Brussels
P.O. Box 80, Sonnhalde 5, 8602 Wangen/ZH, Switzerland

www.icmp-ciem.org



THE GLOBAL VOICE
OF MUSIC
PUBLISHING

Finally, ICMP calls upon the European Commission to propose effective IPR enforcement measures in whatever instrument is to be discussed with the US. The flow of creative content between the EU and the US, beneficial to both parties, is based on the existing copyright framework including the WIPO Internet Treaties. This economic relationship needs a proper enforcement framework that protects artists on both sides of the Atlantic, as otherwise there is a high risk that the creative and innovative sectors cease to develop, leading to job losses and reduced trade in products and services that are dependent on intellectual property laws.

We are open to more in depth and continuous dialogue between stakeholders and policy makers. Both ICMP and our member in the US, the NMPA, are happy to meet with the relevant officials for further discussion, as we believe that enhanced regulatory compatibility would contribute to continued and healthy trade relations between the EU and the US.

Yours sincerely,

Ger Hatton
Director General

Jay Rosenthal
Senior VP & General Counsel NMPA US

cc: Ambassador Miriam Sapiro, Deputy US Trade Representative, Office of the US
Trade Representative
Boris Bershteyn, Acting Administrator, Office of Information and Regulatory Affairs
David Israelite, President and CEO, NMPA US
Ralph Peer, Member of Board of Directors, NMPA and ICMP
Andrew Jenkins, Chair of Board of Directors, ICMP
Coco Carmona, Head of Legal and Regulatory, ICMP

37 Square de Meeus, 1000 Brussels
P.O. Box 80, Sonnhalde 5, 8602 Wangen/ZH, Switzerland

www.icmp-ciem.org

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

Introduction

The US is a strategic partner of the EU. Both the EU and the US are strong promoters of free trade and investment and are among the most open economies in the world. The EU and the US are cooperating at the multilateral level and are engaged in numerous sector-specific bilateral dialogues aiming at increasing transatlantic economic relations. As a political body, the Transatlantic Economic Council (TEC) oversees and facilitates such cooperation with the aim of advancing economic integration between the EU and the US.

To further deepen the transatlantic economic relations, the 28 November 2011 EU-US Summit launched a High Level Working Group (HLWG) on Jobs and Growth tasked with looking at all options to further increase bilateral trade and investment. The Group produced an interim report in June. A final report with recommendations to leaders is due by the end of the year.

The creation of the High Level Working Group on Jobs and Growth is a significant event in transatlantic relations. It is currently injecting strong momentum into the transatlantic economic relationship. The objective is to identify policies and measures to increase EU-US trade and investment to support job creation, economic growth and international competitiveness of EU and US industry. The focus of the Working Group is on options where a common approach is likely to be beneficial for both economies and for the functioning of the global trade architecture. This encompasses, for instance, areas such as tariffs, non-tariff measures, services, investment, intellectual property rights and public procurement.

Building on the good existing relationship and cooperation between the EU and the US in fora such as the TEC and the High Level Regulatory Cooperation Forum (HLRCF), the trade policy initiative envisaged by the HLWG is aimed at shaping the future framework of the EU-US trade relationship. It is consistent with the Commission's view of trade policy as set out in the Communication Trade, Growth and World Affairs of 9 November 2010, which proposed to develop stronger relations with strategic partners such as the US.

This public consultation is intended to enable the gathering of detailed views relating to the future trade and economic relationship between the European Union and the United States. Taking into account the more general initial public consultation published February 2012, it aims at detailing and structuring the feedback of all relevant stakeholders. The results of both consultations will feed into the Impact Assessment DG TRADE is currently preparing. The Impact Assessment will help shaping the position of the Commission with regards to a potential bilateral initiative with the United States in the field of trade policy.

For more on the bilateral trade relation, the objectives and possible options for increased cooperation between the European Union and the United States [please click here](#).

IMPORTANT: Please note that the system allows a time frame of **90 minutes** (= session time) to fill in the questionnaire. When the session time is exceeded, the connexion with the server is lost and your response is not recorded and cannot be retrieved. We therefore strongly recommend to print the questionnaire (button "download PDF version"), elaborate your reply off-line and then insert your replies in the time-limited session.

Statement on the handling of personal data

Questions marked with an asterisk * require an answer to be given.

1. About you

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

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

☐ Yes

☒ No

1.2. Please state the name of your business/organisation/association? * (between 1 and 200 characters)

GIFAS, the French Aerospace Industries Association, has more than 300 members, from major prime contractors and system suppliers to small specialist companies.

They cover the full spectrum of skills from the design, development and production of aerospace systems and equipment to maintenance and operation.

Activities extend from civil and military aircraft and helicopters to engines, missiles and armament, satellites and launch vehicles, plus aerospace, defence and security, major systems, equipment, subassemblies and associated software.

1.3. What is your profile? *

☐ Business

☒ Trade association representing business

☐ Trade union or organisation representing trade unions

☐ Consumer protection agency or representative

☐ Government institution or regulator authority

☐ Other non-governmental organisation

☐ Academic/research institution

☐ Citizen

☐ Other

1.4. If "Other", please specify. * (between 1 and 1500 characters)

1.7. If "Other", please specify. (between 1 and 1500 characters)

1.8. In which country are your headquarters located? *

- ☒ A Member State of the European Union
☐ The United States
☐ Other

1.9. Please specify which country? * (between 1 and 1500 characters)

France

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

2.1. What should be the priorities of the future EU-US trade and economic relationship? *
(between 1 and 4000 characters)

- To open a fair and seamless access to public markets on the basis of/within a level playing field framework.
- To strengthen and enlarge EU-US commerce and trade in order to diversify EU trade balance around the globe and create the conditions for economic growth.
- To build up a transatlantic market, framework and industrial base.
- To create common transatlantic norms and standards in order to avoid unfair competition. These norms and standards could be also applicable to third world countries.
- To promote common ethic business behaviors.

2.2. How should the European Union pursue these priorities?* (between 1 and 4000 characters)

- Analysis of the present situation in force for Governmental procurement.
- Analysis of the major public past procurement results.
- Assessment of the Regulatory burdens on governmental business including the impact of National Security concerns.
- List of all existing and applicable regulations related to governmental affairs: Itar (arms regulation), EAR (), Buy American Act, TAA (Technical Assistance Agreement)..
- Engage transatlantic organizations such as the Atlantic Council.

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

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

*

☐ Yes

☒ No

☐ Do not know / Not applicable

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

*

(between 1 and 1500 characters)

Existing cooperation attempt between US DoD and European MoDs failed, to a certain extent, to provide satisfying results due to regulatory protections on the US side. Many attempts to answer US public procurement also failed due to protectionist measures and trade barriers. In the space sector, cooperation at space agencies level (NASA-ESA-CNES-BNS-DLR...) has not translated into a seamless industrial base due to the regulatory protections on the US side. In some cases, attempts to answer public procurement failed, even with a US industrial Prime contractor, due to a lack of US content requested.

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

*

☒ Yes

☐ No

☐ Do not know / Not applicable

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

(between 1 and 1500 characters)

Economic cooperation should focus primarily on :

- Resolving trade deficit by engaging discussion on regulatory issues in order to simplify and adapt the US regulations related to exports control and security matters (ITAR,...).
- Aligning national procurement regulations so they could offer a fair access to public market for companies on both side of the Atlantic.
- Aligning security standards and requirements in order to build up a level playing field for companies on both side of the Atlantic dealing in the field of Aerospace, Defense and Security.

4. Tariffs

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

*

☐ Yes

☒ No

☐ Do not know / Not applicable

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

*

☐ Yes

☐ No

☐ Do not know / Not applicable

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

(between 1 and 1500 characters)

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

(between 1 and 1500 characters)

5. Non-tariff measures for industrial products

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

☐ Yes

☐ No

☐ Do not know / Not applicable

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

☐ Technical regulations

☒ **Standards**

☒ **Conformity assessment procedures**

☒ **Other**

5.3. If "Other", please specify. ^{*} (between 1 and 1500 characters)

Aerospace sector is concerned by other significant barriers such as :

- Control of the third country nationals.
- Lack of reciprocity.
- Brokering regulations.

These barriers impede transatlantic trade by creating disadvantages for EU industries willing to enter the US market and therefore deficits between Europe and the USA.

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

★

(between 1 and 4000 characters)

Standards

MIL-SPEC (military standards) certified products are automatically approved by FAA (Federal Aviation Administration). In this situation, EU companies are obliged to apply for FAA certification as it is complicated for non-US products to get ML-SPEC certification. On the other hand their US competitors MIL-SPEC certified do not need to get a FAA certification. This situation is creating major constraints and disadvantages for EU companies.

Conformity assessment procedures

Most of EU companies import ITAR control items.

In the context of the on-going process of reform taking place in the US, EU industry would like to ensure that the US reform will guaranty availability (terms and conditions for procuring in the US), predictability (terms and conditions for use and re-export/re-transfer), and security of supply (no unexpected classification changes that will disrupt supply of goods over the life time of the product).

The current rule regarding dual nationals and third country nationals in ITAR does not alleviate the conflict with local law nor does it take into account practical difficulties under local law in collecting and recording data about employees' substantive contacts with proscribed countries or persons. Application of the proposed rule in the current reform would continue to raise human rights/privacy law concerns, particularly regarding questions of nationality and continued allegiance to proscribed countries.

The current situation shows that there is a different handling in the US between the foreign and domestic industry. For example, US sourced articles can benefit from an exemption, allowing them to be returned temporary to the US for repair and replacement. European articles imported in the US cannot benefit from a similar license exemption for temporary return to Europe.

Brokering regulations

- The conflict between the reporting requirements and French/EU laws and regulations, particularly concerning privacy law and Blocking Statute.
- The limited exemptions regarding registration and prior approval requirements.
- Intra-group activities not excluded from the scope of brokering activities.

Buy American Act

This requirement to get/include a sufficient amount of US content (subcontractors) in a project, in order to make a foreign company able to bid for a public contract in the USA, generates a lack of competitiveness for EU companies.

5.5. Indicate how and how much it impacts your business/activity. If possible, provide an

estimate/quantification of the costs of the barriers. * (between 1 and 1500 characters)

- The US defense budget and defense market is by far the largest in the world creating a massive competitive advantage to the US industry on the export markets (by absorbing most of the non recurring cost – scale economy).

Protectionist measures are limiting the access and therefore the amount of foreign purchases.

- More particularly, EU companies are confronted to extra costs:

* Cost for preparing, submitting and tracking re-export and retransfer authorization in addition to the cost of getting a French export license approved for the product that integrates the US content.

* Cost for preparing and submitting reports and information to US suppliers, customers and US regulatory authorities that all ask the industry to prove that a proper compliance plan is implemented, even if such a plan is already required for compliance against the national regulations.

5.6. Indicate what would be the benefits of its removal.

*

(between 1 and 1500 characters)

Its removal would bring added value and create greater EU and US business competitiveness in the global market.

5.7. Please indicate to which level of government the regulatory obstacles relate (multiple answers possible)? *

☒ US Federal / EU level regulation

☒ US States / EU Member State regulation

☐

Do not know / Not applicable

5.8.

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

(between 1 and 4000 characters)

To create a set of measures that will benefit EU companies in several domains (level playing field, business ethics...)

6. Sanitary and phytosanitary obstacles

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

☐ Yes

☒ No

☐ Do not know / Not applicable

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

*

- ☐ Non-processed animal products
- ☐ Non-processed plant products
- ☐ Processed products

6.3. For non-processed animal products (multiple answers possible):*

- ☐ Insufficient or lack of transparency of import requirements
- ☐ Divergences of Federal standards compared to EU standards
- ☐ Divergences of State/local standards within the US
- ☐ Setting up procedure of import requirements
- ☐ Approval facilities
- ☐ Inspections and controls at border inspections post
- ☐ Other

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

(at least 1 answers)

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

6.5. For processed products (multiple answers possible):

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

6.6. If "Other", please specify. (between 1 and 1500 characters)

6.7. Please explain the sanitary or phytosanitary obstacles in detail. * (between 1 and 4000 characters)

6.8. How should the European Union address the specific obstacles? * (between 1 and 4000 characters)

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

*

(between 1 and 1500 characters)

7. Customs procedures, border enforcement and trade facilitation

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

☐ Yes

☒ No

☐ Do not know / Not applicable

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

(between 1 and 4000 characters)

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

(between 1 and 1500 characters)

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

(between 1 and 1500 characters)

8. Protection of Intellectual Property Rights

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

☐ Yes

☐ No

☐ Do not know / Not applicable

8.2. If you are concerned by problems of protection and enforcement of intellectual property rights, please explain the problems you encounter.* (between 1 and 1500 characters)

IPR : systems developed with the contribution of a US design office will result "ITAR tagged". A EU product designed in Europe and manufactured in the USA will fall under ITAR regulation. Hence, the technology associated to this product, although it is protected by EU patent, will fall under the control of the US administration.

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

*

☐ Yes

☒ No

☐ Do not know / Not applicable

8.4. If you are concerned by problems of protection for Geographical Indications or trademarks, please explain the problems you encounter.* (between 1 and 4000 characters)

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

*

(between 1 and 4000 characters)

9. Trade in services

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

- ☐ Yes ☐ No ☐ Do not know / Not applicable

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

*

(between 1 and 5 answers)

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

9.3. If "Other", please specify. (between 1 and 1500 characters)

In MRO activities, the Federal Aviation Administration (FAA) imposes to every new company, which would apply for a certification, to proceed to drugs control in its workshops. This is not suitable with individual rights in France as well as in Europe.

9.4. Please describe the barriers in detail. * (between 1 and 4000 characters)

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

☒ US Federal / EU level regulation

☐ US States / EU Member State regulation

☐ Do not know / Not applicable

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

(between 1 and 1500 characters)

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

(between 1 and 4000 characters)

10. Investment

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

☐ Yes

☐ No

☐ Do not know / Not applicable

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

(between 1 and 4000 characters)

The Committee on Foreign Investment in the United States (CFIUS) which is an inter-agency committee of the United States Government that reviews the national security implications of foreign investments in US companies or operations has the power to review foreign investments – it has a blocking power. CFIUS has the right to restrict foreign investment into US companies or business as well as the access to federal market by foreign owned companies needing a SSA or Proxy.

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

*

☐ US Federal / EU level regulation ☒ US States / EU Member State regulation ☐ Do not know / Not applicable

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

*

(between 1 and 1500 characters)

Costs of preparing and submitting a demand of acquisition (lawyers...). For the SME investing in the US one potential barrier is associated with the cost of doing business in another country. On this issue the USA, one constraint is related to the necessity to do business through lawyers who are often making things much more complicated than needed, just to justify fees, which often can go up to 10 or 20% of the investment.

The second constraint appears when the company is involved with ITAR issue or CFIUS. It is a very expensive lengthy process, even with none strategic products services or issues. It can take between 18 and 36 month to go through the entire process. These barriers are limiting direct investment in the USA due to the fact that companies simply stop the process as they have no grip on it. The cost associated with the ITAR issues raised due the acquisition of a US company by French Company. These costs are never less than 100K\$ and often much more, and the cost due to the CFIUS process well exceed 100K\$ too.

10.5. If you are concerned by barriers to investment, how should the European Union address the issue? * (between 1 and 4000 characters)

To establish a dialogue between the US and the EU to define principles of reciprocity, taking into account national rules in Europe.

To discuss precise topics when they occur during bilateral EU/US meetings.

11. Public Procurement

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

☐ Yes

☐ No

☐ Do not know / Not applicable

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

(between 1 and 4000 characters)

In the defence sector, TAA, the Trade Agreements Act, requires that the US Government may acquire only "US – made or designated country end products". This act makes it already impossible for non US companies to have access to the documentation prior to bidding for a public contract.

Moreover, the impact of the National Security concerns in the US does not facilitate cooperation and partnerships. In the civil sector, EU companies have a very limited access to research and development project financed by NASA and FAA, even when they have an industrial presence in the US territory.

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

☐ US Federal / EU level regulation ☒ **US States / EU Member State regulation**

☐ Do not know / Not applicable

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

(between 1 and 1500 characters)

- For a prime contractor, TAA, or Buy American Act, makes it mandatory to establish a US factory for local sales. This situation creates additional cost compared to the US competitor.
- For an SME, no possible bid, or necessity to create a joint-venture with a local partner (with possible risk for IPRs).
- SESAR and NEXTGEN are the EU and US ATM systems under development. Whereas US companies are working on SESAR project (Honeywell), using EU funds, and are able to participate in the definition of future standards. NEXTGEN remains with very limited possibility of cooperation for EU companies (subcontracting only).
- EU/US cooperateur project failed to develop under FP7 (...).

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

*

(between 1 and 4000 characters)

UE should involve in order to ensure a level playing field environment offering the possibility for US companies to bid in European public procurement if European companies are allowed to bid in a US public procurement, and by making sure that national security issues (Itar, Buy American Act, ...) are not impeding the transatlantic trade anymore/or by limiting the impact of national security constraints. Trade figures should be regularly compared (impact assessment) to evaluate (...).

EU should sent commissions and delegations to the US in a similar way, US commissions do when they come to Europe in order to study and report an states' and industrials' processes... For instance, in 2012, the United States International Trade Commission published a benchmark on business jet industry "Structure and factors affecting competitiveness" after investigating in different EU countries.

12. Competition issues

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

☒ Yes

☐ No

☐ Do not know / Not applicable

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

	Yes	No	Do not know / Not applicable
12.2.1. Anti-trust *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
12.2.2. Mergers *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
12.2.3. Liberalisation *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
12.2.4. State Aid *	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

12.3. What should be the European Union priorities? * (between 1 and 4000 characters)

13. Facilitating the participation of small and medium sized enterprises (SMEs) in the transatlantic market place

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

(between 1 and 4000 characters)

SMEs are concerned by all the previous sections of this questionnaire (level playing field, export control procedures, etc...)

13.2. In your view/experience, how could SMEs better benefit from economic opportunities in transatlantic trade and investment relationships? * (between 1 and 4000 characters)

SMEs would benefit by being part of the US supply chain. As a first step, they would benefit by having a legal support as US procedures are both costly and timely expensive.

14. Impact on Consumers

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

*

☒ Yes

☐ No

☐ Do not know / Not applicable

14.2. If yes, what impact do you expect?

	Yes	No	Do not know / Not applicable
14.2.1. Lower Prices *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
14.2.2. Higher prices *	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
14.2.3. Larger choice of products *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
14.2.4. Smaller choice of products *	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
14.2.5. Other	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

14.3. If "Other", please specify. (between 1 and 1500 characters)

More efficient products (CO2 emissions)

15. Environmental Impact

15.1. Do you expect impacts on the environment in the context of an enhanced EU-US trade cooperation? *

☒ Yes

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

	Positive	Negative	Do not know / Not applicable
15.2.1. Air pollution *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.2.2. Water pollution *	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
15.2.3. Ground pollution *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.2.4. CO2 emissions *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.2.5. Impact on bio-diversity *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.2.6. Other	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

15.3. If "Other", please specify. (between 1 and 1500 characters)

Noise reduction

15.4. Given the importance of commitments on environmental protection as underlying elements for international economic relations, how could the European Union and United States cooperate to further promote the adherence to and the strengthening of international principles, rights and agreements on environmental protection? * (between 1 and 1500 characters)

A closer cooperation of EU and US on environmental commitments could lead to higher standards on environmental protection through the definition of a common agenda. A unilateral approach from the EU side (ETS, Reach) does not produce the expected results as it leaves aside a major player of the aerospace industry. It creates a disadvantage for the European industry vis-à-vis the US industry which does not need to apply to these rules.

16. Social Impact

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

*

☐ Yes

☒ No

☐ Do not know / Not applicable

16.2. Please explain * (between 1 and 1500 characters)

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

	Positively	Negatively	No change	Do not know / Not applicable
16.3.1. In the EU: *	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16.3.2. In the US: *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

	Positively	Negatively	No change	Do not know / Not applicable
16.4.1. In the EU: *	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
16.4.2. In the US: *	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

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

	Positively	Negatively	No change	Do not know / Not applicable
16.5.1. In the EU: *	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
16.5.2. In the US: *	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

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

recognised principles, rights and agreements on labour and decent work? * (between 1 and 1500 characters)

17. Other issues

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

(between 1 and 4000 characters)

The questionnaire should address the issue of the Euro-dollar conversion and parity.

17.2. Your comments ... (between 1 and 1500 characters)

Background documents

Statement on the handling of personal data: <http://trade.ec.europa.eu/doclib/html/149599.htm>



Marine House
18-22 Baker Street
Weybridge
Surrey
KT13 8AU

Tel 01932 850020
Fax 01932 850033

M. Fernando Perreau de Pinninck
Unit F3 Tariff and Non-Tariff Negotiations, Rules of Origin
DG Trade
European Commission
1049 Brussels
BELGIUM

October 31, 2012

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

Dear Mr. Perreau de Pinnick,

The International Fur Trade Federation ("IFTF") is pleased to provide these comments in response to the joint U.S.-EU request for input regarding a consultation towards reducing excessive regulatory costs, unjustified regulatory differences, and unnecessary red tape while respecting the protection of public health, safety, welfare and the environment.¹

The IFTF was formed over 60 years ago to be the voice of the fur trade, protect the fur trade's interests, promote innovation and high standards and present a factual image of the fur industry. The IFTF represents 42 national fur trade associations and organizations from 35 countries. Members are drawn from the entire fur supply chain: farmers, trappers, auction houses, merchants, brokers, buyers, dressers and dyers, designers, manufacturers, wholesalers, marketing organizations and retailers. The IFTF is headquartered in London with subsidiary offices in Beijing and Brussels.

Given the breadth of the IFTF's membership and the international scope of the fur trade, the IFTF is uniquely positioned to understand the complexities of varying regulatory structures. As discussed below, the U.S. and EU requirements for fur labelling stand in stark contrast to one another, the result of which is that industry participants are forced to invest resources in complying with two very different regimes simply to be able to sell their products in both places.

Set forth below is a discussion of the U.S. and EU for labelling laws, their effect on industry and proposed steps to eliminate unnecessary burdens. The IFTF appreciates the opportunity to offer these remarks and looks forward to participating in future discussions.

¹ Also see 77 Fed. Reg. 59702 (September 28, 2012).

I. The U.S. Fur Labeling Requirements are Detailed and Burdensome

Fur products sold in the U.S. are governed by the Fur Products Labelling Act (“FPLA”) and its implementing regulations.² Passed in 1951, the FPLA broadly applies to “any article of wearing apparel made in whole or in part of fur or used fur” with certain limited exceptions.³ The FPLA is a strict liability statute that makes it a violation of the U.S. Federal Trade Commission Act (“FTC Act”) to introduce, manufacture for introduction into commerce, sale, offer for sale, advertise, transport or distribute any fur product which is misbranded or falsely or deceptively advertised or invoiced.⁴ A fur product is considered misbranded or falsely or deceptively advertised or invoiced if it does not meet the following requirements:

(2) if there is not affixed to the fur product a label showing in words and figures plainly legible -

(A) the name or names (as set forth in the Fur Products Name Guide⁵) of the animal or animals that produced the fur, and such qualifying statement as may be required pursuant to section 69e (c) of [the FPLA];

(B) state that the fur product contains or is composed of used fur, when such is the fact;

(C) state that the fur product contains or is composed of bleached, dyed, or otherwise artificially colored fur, when such is the fact;

(D) state that the fur product is composed in whole or in substantial part of paws, tails, bellies, or waste fur, when such is the fact;

(E) state the name, or other identification issued and registered by the Commission, of one or more of the persons who manufacture such fur product for introduction into commerce, introduce it into commerce, sell it in commerce, advertise or offer it for sale in commerce, or transport or distribute it in commerce;

(F) state the name of the country of origin of any imported furs used in the fur product;⁶

It is also an unfair and deceptive act, and therefore a violation of the FTC Act to do any of the following things:

- Remove or mutilate a label on a fur product prior to the time any fur product is sold and delivered to the ultimate consumer, except as specifically allowed in the FPLA;
- Fail to maintain records of any fur product labels substituted for previous labels.⁷

The Federal Trade Commission (“FTC”) is charged with enforcing the FPLA. Companies that sell fur can file a guaranty with the FTC attesting that their products are not mislabeled or deceptively advertised. Notably, the guaranty is not a mere statement of intent to comply. It

² See 15 U.S.C. § 69 and 16 C.F.R. § 300, et seq.

³ Id. at § 69(d).

⁴ Id. at § 69a(a)-(e).

⁵ The Fur Products Name Guide is found at 16 C.F.R. 301.0. It lists the required animal names by genus and species for all animal types commonly used for fur products.

⁶ 15 U.S.C. §§ 69b and c. This list provides only a snapshot of the labeling requirements that apply to fur products sold in the U.S. The regulations found at 16 C.F.R. § 300, et seq. set forth the myriad requirements for fur labeling and advertising.

⁷ Id. at § 69a(d) and (e).

must be signed under penalty of perjury.⁸ Persons found guilty of intentional violations of the FPLA may also be subject to a criminal penalty.⁹

II. EU Fur Labeling Requirements are Broad and Practical

By comparison, the EU fur labelling requirements are remarkably streamlined. In September 2011, the European Commission passed a law that harmonizes textile labelling, which includes fur labelling.¹⁰ With regard to fur products, the EC states as follows:

It is appropriate to lay down rules concerning the labelling or marking of certain textile products which contain non-textile parts of animal origin. This Regulation should, in particular, set out the requirement to indicate the presence of non-textile parts of animal origin on the labelling or marking of textile products containing such parts, in order to enable consumers to make informed choices. The labelling or marking should not be misleading.

The guidance note states that the label of products containing these materials are to include the phrase "Contains non-textile parts of animal origin". The purpose of this change is to enable consumers to make informed choices between buying textiles containing real fur or leather - or fake fur or leather.

The Regulation does not require the manufacturer to include a sewn-in label or to print directly on to the product. Rather, hang tag labels or other temporary labels must simply be durable and legible.

III. These Regulatory Divergences Should Be Addressed

The U.S. and EU are advanced economies with sophisticated consumer protection regimes. Those regimes protect the consumer by providing information that enables informed purchasing decisions by the retail consumer. In the fur retail sector, these objectives are implemented in the U.S., and more recently in the EU, through retail labelling requirements that are specific to fur products.

The divergences, however, between the applicable U.S. and EU requirements are significant, and given the global nature of the fur market, the divergences impose significant costs and burdens on enterprises that are committed to complying with the applicable standards. This is particularly true with respect to small and medium-sized enterprises, which characterize the vast majority of the IFTF's members and other entities engaged in the production, processing, assembly, marketing, and sale of furskins and fur products, and the importation and exportation of those products.

The current U.S.-EU consultations provide an unique opportunity for the two governments to explore ways to minimize the differences in the labelling requirements applicable to the fur

⁸ The prescribed form is available at 16 C.F.R. § 303.38. The same form is required for the Wool Products Labeling Act and the Textile Fiber Products Identification Act.

⁹ 15 U.S.C. § 69i.

¹⁰ Regulation (EU) No. 1007/2011.



sector, without undermining the objective of providing relevant information to the consumer, objectives that are reflected in legislation in both the U.S. and the EU. The IFTF appreciates the opportunity to participate and support this discussion and looks forward to further development of these efforts.

Sincerely,

Mark Oaten
Chief Executive Officer
International Fur Trade Federation

KADINOVA Desislava (TRADE)

From: EMBERGER Geraldine (TRADE)
Sent: 15 January 2013 18:37
To: TRADE F3 SECRETARIAT; ROELAND Christophe (ENTR)
Subject: RE: TBC Submission: Regulatory Cooperation in Financial Services

Follow Up Flag: Follow up
Flag Status: Flagged

No, a fresh one, colleagues in B1 are informed. We will also need a letter of acknowledgement and ENTR will need to add this to their webpage.

From: TRADE F3 SECRETARIAT
Sent: Tuesday, January 15, 2013 6:23 PM
To: EMBERGER Geraldine (TRADE); ROELAND Christophe (ENTR)
Subject: FW: TBC Submission: Regulatory Cooperation in Financial Services

Is this a fresh contribution to EU-US HLWG or it is a separate contribution?

Thanks, sorry for the stupid question, we all just received it yesterday
Dessy

Desislava KADINOVA
Assistant to the Head of Unit



European Commission
DG TRADE
Unit F3

CHAR 09/36
B-1049 Brussels/Belgium
+32 2 295 61 97/ 296 74 19
TRADE-F3-SECRETARIAT@ec.europa.eu
dessislava.KADINOVA@ec.europa.eu

From: Hendrike Kuehl [<mailto:hkuehl@transatlanticbusiness.org>]
Sent: Monday, January 14, 2013 5:47 PM
To: bbershteyn@omb.eop.gov; Miriam_Sapiro@ustr.eop.gov; ENTR DIRECTOR GENERAL; DEMARTY Jean-Luc (TRADE); TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: [Douglas M Bell@ustr.eop.gov](mailto:Douglas_M_Bell@ustr.eop.gov); Mullaney, Dan (Daniel_Mullaney@ustr.eop.gov); David_Weiner@ustr.eop.gov; [Katherine R. Kalutkiewicz@ustr.eop.gov](mailto:Katherine_R_Kalutkiewicz@ustr.eop.gov); Mark.Sobel@do.treas.gov; jweiss@omb.eop.gov; ahunt@omb.eop.gov; mfroman@nss.eop.gov; [Janis P Lazda@nss.eop.gov](mailto:Janis_P_Lazda@nss.eop.gov); david.defalco@trade.gov; Kim Tuminaro;; PollardRA@state.gov; Beryl Blecher; Bryan, Elena (Elena_Bryan@ustr.eop.gov); BakerS@state.gov; SIERRA BRAGADO Purificacion (ENTR); GARCIA BERCERO Ignacio (TRADE); SCHLEGELMILCH Rupert (TRADE); LEVIE Damien (TRADE); EMBERGER Geraldine (TRADE); RUBIN DE CERVIN Almoro (MARKT); MERLIN Martin (MARKT); PHILIPSON Agnete (MARKT); ROELAND Christophe (ENTR); Tim Bennett; Claire Layton; Justine Korwek; Emanuel Adam; Hilary Sama
Subject: TBC Submission: Regulatory Cooperation in Financial Services

Dear Sir/Madam,

The Transatlantic Business Council is pleased to submit suggestions on financial services in a potential agreement between the EU and the U.S. to liberalize trade, investment and services.

Financial services are a key element to facilitate transatlantic trade. This submission includes proposals for EU-U.S. regulatory cooperation in the areas of banking, securities, infrastructure,



1

2

3

4

insurance, accounting and auditing. We hope that these recommendations will be considered as the deliberations of the High Level Working Group are progressing.

Kind regards,

Hendrike Kuehl

Transatlantic Business Council

US Director || hkuehl@transatlanticbusiness.org || www.transatlanticbusiness.org || (office) +32-2-5140301 || (cell) +32-4-97-484-881 ||

Follow our tweets @TBC_Council



VALASTRO Silvia (TRADE)

From: Dominick Moxon-Tritsch <dmoxon-tritsch@iftf.com>
Sent: 31 October 2012 16:42
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH; PERREAU DE PINNINCK Fernando (TRADE)
Cc: Mark Oaten; Larry Lasoff; Isabelle Roccia
Subject: EU and US call for input on regulatory issues for possible future trade agreement
Attachments: EU US consultation October 2012_IFTF submission[2].pdf

Dear M. Perreau de Pinninck, Sirs

Please find attached the consultation response of the International Fur Trade Federation (IFTF) to the joint EU-US consultation on transatlantic regulatory issues in view of a possible future trade agreement.

A similar contribution has been submitted to the authorities in the United States managing the consultation on the US side for and on behalf of IFTF by Larry Lassof of Kelley Drye, as legal counsel to this organisation.

IFTF welcomes the recent initiatives taken jointly by the EU and the US to strengthen their trade and economic relations and hopes that this contribution will be a useful contribution to the discussion.

Representing trade associations in over 36 countries, with members in many European countries, the U.S. as well as China, Russian and Canada, IFTF is ideally placed to offer constructive views on trade challenges encountered by the a rapidly growing agricultural commodity sector.

Should you wish to discuss further any of the issues raised herein, M. Mark Oaten IFTF's CEO and myself are at your disposal.

Yours truly

Dominick Moxon-Tritsch
Director of Government Relations, Solicitor (England & Wales)
International Fur Trade Federation

Telephone: +44 (0)1932 850020
Mobile telephone: +44 (0)7557 743889
Skype: dmt_iftf
Fax: +44 (0)1932 850033

****Email Confidentiality Notice****

This message is private and confidential and its contents may be protected by legal professional privilege. If you have received this message in error, please notify the sender and delete it from your system.

VALASTRO Silvia (TRADE)

From: TRADE F3 SECRETARIAT
Sent: 15 January 2013 16:07
To: Ger Hatton; jrosenthal@nmpa.org; Ralph Peer; disraelite@nmpa.org; Jenkins, Andrew; Coco Carmona
Cc: DE LUSIGNAN Paul (TRADE); DUPUIS Philipp (TRADE); EMBERGER Geraldine (TRADE); GARCIA BERCERO Ignacio (TRADE); GEHL Fabien (TRADE); GOUX Sebastien (SANCO); GREMMINGER Michael (SG); KAIZELER Ivone (TRADE); LEVIE Damien (TRADE); MINOR Jacqueline (SANCO); MUSALL Benjamin (TRADE); NEIRA Pablo (TRADE); PERREAU DE PINNINCK Fernando (TRADE); ROELAND Christophe (ENTR); SCHARRENBORG Robertus (SG); SCHLEGELMILCH Rupert (TRADE); SCHMITZ Jan (TRADE); SORENSEN Carsten (TRADE); SOURMELIS Petros (TRADE); WEIGL Ulrich (TRADE); BRUNKO Patricia (SANCO); DANIEL Ewelina (ENTR)
Subject: EU-US HLWG Joint Solicitation on regulatory issues, acknowledgement of receipt
SentItemsFolder2ndMbxAddin: 00000000242C326C33DD3B44A0E37DEA21CC54830100AA1FCCD1DA3D214096108EED04056D4C0000008131F30000



ICMP - EU US call
for input o...

Dear Mr Hatton, Mr Rosenthal, Mr Israelite, Mr Peer and Mr Bershteyn,

We hereby acknowledge the receipt of your contribution to the Joint EU-US solicitation on how to promote transatlantic regulatory compatibility.

Contributions will now be examined by the Commission services and the US administration in view of informing the joint final report of the *High Level Working Group on Jobs and Growth* and exploring the development of action plans to enhance regulatory compatibility in the course of possible negotiations for a trade and investment agreement. The report of the High Level Working Group will make recommendations to EU and US leaders as to the opportunity of such bilateral negotiations.

As a next step, the Commission services and the US Administration will discuss the possibility to gather EU and U.S. regulators, economic policy agencies and stakeholders early 2013 to examine the various suggestions made.

All contributions to the consultation will be made available on the European Commission's DG TRADE and ENTR websites as soon as possible, unless confidentiality has been requested.

Should you require any further information, please contact:

Directorate General for Enterprise and Industry - Mr. Christophe Roeland (tel.: 02/29 67257),
christophe.roeland@ec.europa.eu

Directorate General for Trade - Ms. Geraldine Emberger, (tel.: 02/29 92068),
geraldine.emberger@ec.europa.eu

With our best regards,

Ignacio Garcia Bercero

Director DG TRADE

Didier Herbert

Director DG Enterprise



Position Paper

EU-US Solicitation High Level Working Group

Our reference:	IAR-12-309	Date:	31 October 2012
Referring to:	Consultation on regulatory issues for possible EU-US FTA		
Related documents:			
Contact person:	Hannah Grant, Head of International Affairs & Reinsurance	E-mail:	grant@insurancееurope.eu
Pages:	2	Transparency Register ID no.:	33213703459-54

Summary

Insurance Europe, European insurance and reinsurance federation, based in Brussels, represents through its 34 member bodies — the national insurance associations — insurance and reinsurance undertakings, which account for around 95% of total European premium income.

The transatlantic relationship constitutes the largest economic relationship in the world with bilateral trade and investment in the insurance sector alone exceeding 185 billion dollars a year. Not only is close co-operation important for transatlantic business flows, but the EU and the US insurance sectors together represent 74% of the global premium income. By working closer together we can make an important contribution to the shape of global (re) insurance supervision and regulation. However, as other international insurance markets grow and become increasingly sophisticated in their regulatory approach, an increased focus on our bilateral relationship provided by the EU-US High Level Working Group is not only timely for transatlantic business flows but also for the international footprint of companies located both sides of the Atlantic.

Insurance Europe has closely followed and supported the work of the High Level Working Group since its establishment - submitting comments to the scoping exercise at the beginning of the year and issuing a joint statement with the American Council of Life Insurers following the publication of the High Level Working Groups interim report. Consistent with our previous submissions we would like to again take this opportunity to request the High Level Working Group include the insurance sector within its final recommendations.

We also welcome the explicit request for comments relating to 'regulatory issues' in the most recent EU-US solicitation. As highlighted in our introductory comments, many large European insurers have a significant amount of their premium originating from the US which is either transacted on a cross border basis, or through establishing branches or subsidiaries in the US. The companies conducting these business transactions increasingly find themselves subject to duplicative regulatory requests; with supervisors, including those only supervising solo entities, wanting to gain a more holistic view of entire insurance groups operations. We would therefore, like to see greater recognition of robust group supervision conducted elsewhere. In addition, through the removal of regulatory restrictions to cross border trade, such as the statutory reinsurance collateral requirements in the US, and support for open markets continuing into the future, we believe our important economic relationship has the potential for growth.

In order for these desirable goals to be achieved it is important that supervisors gain a greater mutual understanding of each other's regulatory practises which should in turn facilitate informed decision making on where the same outcomes are already achieved through different means and identification of areas where

greater convergence would be beneficial. To these ends we are very supportive of the insurance dialogues currently being conducted between the EU-US and especially the recent publication of a draft Technical Report summarising the output of their dialogues¹.

Publication of the draft report signifies the end of Phase I of this exercise. Phase II which has now commenced is intended *"to lead to policy decisions by the respective organisations, regarding whether and how to achieve further harmonisation in regulation and supervision"*. The project is scheduled to come to a conclusion by December 31st 2012. Publication of this report is noteworthy not just in terms of the concrete outcomes which are intended to follow but also the openness and transparency it provides to stakeholders. These regulatory dialogues have been operating, albeit not so intensively, for many years and have previously provided little stakeholder feedback so this increase in transparency is a welcome change.

To conclude, Insurance Europe does not look to the High Level Working Group to duplicate insurance dialogues already going on in other forums, but that political support is given to the insurance dialogues to ensure:

- Insurance regulatory dialogues continue into the future
- Milestones agreed to at the end of 'Phase II' are met in a timely manner; and
- Increased transparency to stakeholders continues to be provided.

For more detail on what next steps we would like to see taken in the EU-US insurance dialogues please find attached our recent response to the EU-US Technical Committee report.

Insurance Europe is the European insurance and reinsurance federation. Through its 34 member bodies — the national insurance associations — Insurance Europe represents all types of insurance and reinsurance undertakings, eg pan-European companies, monoliners, mutuals and SMEs. Insurance Europe, which is based in Brussels, represents undertakings that account for around 95% of total European premium income. Insurance makes a major contribution to Europe's economic growth and development. European insurers generate premium income of over €1 100bn, employ nearly one million people and invest almost €7 500bn in the economy. www.insuranceeurope.eu

¹Draft report on the EU-US Dialogue Project, September 27th 2012
https://eiopa.europa.eu/fileadmin/tx_dam/files/consultations/consultationpapers/EU-US_Dialogue_Project_Report_for_Consultation.pdf

October 24, 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: US-EU Regulatory Compatibility

We, the undersigned associations, write to strongly encourage the U.S.-EU High Level Working Group on Jobs and Growth (Working Group) to endorse ambitious and well-developed regulatory cooperation provisions as part of any recommended negotiation that seeks a high-standard transatlantic trade and investment agreement. Strengthening economic ties and enhancing transatlantic regulatory cooperation through an agreement that would include both goods and services, including financial services, are essential to eliminating unnecessary regulatory divergence that may act as a drag on economic growth and job creation.

U.S. and EU regulators already cooperate extensively with one another, both directly and in the context of broader formal arrangements such as the G-20 dialogue, the Transatlantic Economic Council (TEC), the U.S.-EU High Level Regulatory Cooperation Forum (HLRCF), and the U.S.-EU Financial Markets Regulatory Dialogue. However, these arrangements can be made much more effective and should include enhanced opportunities for dialogue with stakeholders. Any agreement should enhance current efforts and develop the regulatory cooperation mechanisms needed to unlock the true potential of an agreement.

Such provisions should comprehensively and ambitiously address traditional technical barriers to trade and sanitary/phyto-sanitary issues. These provisions should also expressly encourage regulators to work together to reduce and eliminate duplicative and inconsistent measures in existing regulations and where appropriate utilize recognition arrangements. In addition, the agreement should work to limit future unwanted regulatory divergence by promoting a better understanding of the impact significant regulations may have on the transatlantic market and facilitate information sharing, which will ensure regulatory decisions when appropriate, reflect the marketplace, are fact based, grounded in sound science, and undergo thorough regulatory and cost-benefit analysis.

We thank you for your consideration and look forward to the opportunity to assist the Working Group in developing and implementing regulatory cooperation provisions that maximize benefits to stakeholders, the government and the public.

Advanced Medical Technology Association
American Automotive Policy Council
American Chemistry Council
American Council of Life Insurers
Association of British Insurers
Association for Financial Markets in Europe
Biotechnology Industry Organization
BUSINESSEUROPE
Business Roundtable
Coalition of Service Industries
The Council of Insurance Agents and Brokers
Emergency Committee for American Trade
European-American Business Council
European Federation of Pharmaceutical Industries and Associations
European Chemical Industry Council
Financial Services Roundtable
Insurance Europe
Medical Imaging Technology Alliance
National Association of Manufacturers
National Foreign Trade Council
National Electrical Manufacturers Association
Personal Care Products Council
Pharmaceutical Research and Manufacturers of America
Securities Industry and Financial Markets Association
TheCityUK
The TransAtlantic Business Dialogue
Transatlantic Coalition on Financial Regulation
U.S. Chamber of Commerce
United States Council for International Business



National Electrical Manufacturers Association

Representing Electrical and Medical
Imaging Equipment Manufacturers
www.nema.org

October 31, 2012

Boris Bershteyn
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
1650 Pennsylvania Avenue, NW
Washington, DC 20503

Daniel Calleja Crespo
Director General
Directorate General for Enterprise and Industry
European Commission
B-1049 Brussels, Belgium

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

Jean-Luc Demarty
Director General
Directorate General for Trade
European Commission
B-1049 Brussels, Belgium

Dear Administrator Bershteyn, Director General Crespo, Ambassador Shapiro, Director General Demarty,

Thank you for the opportunity to provide the following comments on United States-European Union trade and economic relations on behalf of our more than 400 member companies. At NEMA we believe there is significant potential to strengthen further U.S.-EU trade and investment relations to support mutually beneficial job creation, economic growth and international competitiveness.

NEMA is the U.S. association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Arlington, Virginia, USA. Our member companies manufacture a diverse set of products including power transmission and distribution equipment, lighting systems, factory automation and control systems, and medical diagnostic imaging systems. Worldwide annual sales of NEMA-scope products exceed \$120 billion. The electrical equipment and medical imaging industries together support more than one million U.S. jobs.

NEMA is pleased with the engagement and commitment of U.S. and EU leaders in the High-Level Working Group on Jobs and Growth (HLWG) as well as the High Level Regulatory Cooperation Forum (HLRCF).

Your September 7 solicitation of comments from the public stated your

hope to receive detailed input on differences between existing regulation in the United States and Europe that may impose unnecessary costs and burdens on American businesses, and on priority areas where we should cooperate on future regulations affecting new and innovative growth markets and technologies, particularly for small and medium sized businesses.

Furthermore, your Sept. 7 solicitation invited “views on how to promote greater transatlantic **regulatory compatibility** generally” and in particular economic sectors (*emphasis added*).

We note that the U.S. and its partners in the Trans-Pacific Partnership negotiations have set a very high goal for a forward-looking agreement. In general, we believe that this level of ambition should be the “floor” from which a new U.S.-EU pact must be built, rather than a “ceiling” that might restrain negotiators.

That said, in general negotiators should make every effort to reduce uncertainty and raise the level of confidence and assurance for electrical manufacturers and associated services providers that want to trade and invest across the Atlantic.

Barriers to trans-Atlantic trade and investment are already relatively low, given low customs duties, high trade volumes and significant levels of cross-investment. According to U.S. government data, the value of U.S.-EU trade in electrical and medical equipment within NEMA’s scope in 2011 totaled approximately \$15.7 billion; data through August 2012 indicated an expected increase for the full year of 2012.

New Industries and Technologies

The U.S. and EU must continue their focus and redouble their efforts to prevent barriers to trade in new and emerging industry sectors. From NEMA’s point of view, these industry areas include Smart Grid, electrical vehicle (“e-mobility”) supply equipment, and advanced lighting technologies. The U.S. and EU should work closely and collaboratively with their industry stakeholders to define open and compatible standards in these areas to prevent the creation of technical barriers to trade.

As an example, Intelligent Transportation Systems (ITS) technologies are also a growing export sector largely based on voluntary consensus industry standards, including some developed with the support of the U.S. Department of Transportation. Many of these standards have been recognized, adopted and are being used in a growing number of countries, including in the European Union. The EU should recognize and adopt these standards more broadly rather than invest scarce resources in developing EU-only standards.

The Medical Imaging and Technology Alliance (MITA), a division of NEMA, represents manufacturers of medical imaging, radiation therapy, and radiopharmaceutical products that operate in the U.S. and EU. There are several opportunities within the medical imaging industry to boost trade and investment between the U.S. and EU in order to support mutual job and economic growth as well as to increase the international competitiveness of our industries. By joining forces on matters of common interest to better communicate, coordinate and collaborate, the U.S. and EU can work together to reduce unnecessary regulation and improve market access to life-saving medical equipment. This can be done by mutually identifying topics and trends with global industry impact, developing joint positions, leveraging the benefits of international standards, advocating for efficient and reasonable regulation that promotes innovation, supporting harmonization of regulatory frameworks and streamlining clearance processes. By working together, millions of people around the world will benefit from improved access to these life-saving technologies.

Ongoing negotiations under the auspices of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal are nearing a decision to extend export controls and trade prohibitions to cover shipments of used products for repair, refurbishment and reuse. The Convention, an agreement among 175 countries, currently governs trade in hazardous wastes but could be expanded dramatically under proposals from the European Union, with support from environmental non-governmental organizations.

The U.S. is participating in the negotiations but is not currently a full signatory to the Basel Convention, so U.S. influence is limited. The EU proposals would apply hazardous waste controls and trade bans to exports of most used electrical and electronic equipment resulting in massive costs on manufacturers that rely on transboundary movement of legitimate (non-waste) equipment for authorized service, repair, refurbishing, remanufacturing, and root-cause analysis activities.

While the proposals are intended to address the real issue of illegal shipments of “e-waste”, they are overly expansive and would, in effect, eliminate the broad environmental, economic and social benefits arising from repair, refurbishing, remanufacturing, and reuse of electrical and electronic equipment. The U.S. and EU must work with stakeholders and like-minded parties to the Basel Convention to impress upon all countries the need to preserve the right to move legitimate shipments of used electrical and electronic goods for assessment, repair and refurbishment.

In addition, several countries, including Brazil, China and India, either have or are considering import bans for all remanufactured equipment despite the fact that if such remanufacturing were to be done in-country it is accepted. This clearly is not only a safety issue. Recognizing that some countries may want to prevent importation of products that are headed for their solid waste facilities rather than recycling or reuse, NEMA and MITA encourage the U.S. and EU to continue to work with these countries and others to recognize the value of high-quality remanufactured equipment, especially in the medical imaging industry.

There is a great deal of inequality in healthcare expenditures between more and less developed countries, and as technology advances, costs go up, which makes the inequality worse. Remanufactured medical imaging equipment save lives by improving access to technology that otherwise may not be available; saves money by lowering the cost to purchase advanced medical technologies; and saves resources, which allows for the re-use of products that contain precious metals and keeps those materials out of landfills.

Medical imaging equipment and other advanced medical devices are designed to last for as many as twenty years or even longer. Many doctors in developed countries purchase new products every few years to keep pace with the most recent technological advances, therefore there are a number of safe, advanced, fully-functioning devices that can be used for many more years and at reduced cost.

MITA members have years of experience with remanufactured products, which fall under U.S. Food and Drug Administration supervision to ensure that products are properly certified and meet the necessary specifications. The U.S. and other developed countries have used remanufactured equipment for quite some time and pre-owned products make up a significant percentage of the U.S. market. A white paper on

good remanufacturing practices for medical imaging equipment is also available at http://www.cocir.org/uploads/documents/46-907--39-final_grp_report_2009.pdf. The paper was published in 2009 by the global medical imaging industry, represented by MITA and its European and Japanese counterpart industry organizations COCIR and the Japan Industries Association of Radiological Systems (JIRA). The paper proposes principles for remanufacturing to ensure that only quality remanufactured medical imaging equipment be introduced into markets.

Regulatory

U.S. industries and the U.S. Government have frequently complained about the EU propensity to establish regulations lacking in solid technical justification and whose burdens of implementation are not proportionate to intended consumer or environmental benefits. Typically, these regulations are based on the “precautionary principle” and are developed with procedures that are not transparent to all stakeholders, including the U.S. electrical manufacturing industry and other trading partners. Further, stakeholders find they have no way to hold EU authorities accountable for the regulations produced and implemented. The U.S. must refrain from adopting the EU approach to regulatory development and implementation.

Trans-Atlantic harmonization of existing regulations in and of themselves is not the goal NEMA would recommend. That said, the U.S. and EU should work together to minimize the barriers that existing regulations present to trade in safe products in the spirit that regulations should not be trade-distorting. The two partners should share data with each other that enables regulatory comparisons and enables mutual compliance.

Improvements to regulatory compatibility in the medical imaging sector should be achieved via mutual recognition of each other’s quality management systems and audits, of a singular standard for a medical device marketing application with electronic submission capabilities, and of a singular standard for a Global Unique Device Identification Database for medical devices. For a detailed discussion of these recommendations on medical imaging equipment, please refer to the recent joint paper of COCIR and MITA provided under separate cover.

In the electrical equipment sector, the two parties should consider launching joint initiatives to improve market surveillance and enforcement of their regulations.

Our industry is committed to working with USTR and OMB to engage with the EU on questions of governance and regulatory disciplines, and to find solutions to its systemic regulatory problems, ensuring justification, transparency and openness in development of directives, as well as “national treatment” and accountability in their application.

Standards and Conformity Assessment

The EU has failed to adopt the principles determined by the World Trade Organization (WTO) Technical Barriers to Trade Committee for the development of international standards

- openness
- transparency
- impartiality and consensus
- relevance and effectiveness,
- coherence
- development

and that in these terms an “international standard” is neither automatically nor limited to a standard that is developed by one or more of the three Geneva-based standards development organizations (SDOs) – the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), and the International Organization for Standardization (ISO). The EU should recognize and adopt the WTO TBT definition formally and in practice.

The EU authorities should recognize and leverage the fact that non-EU, non-Geneva SDOs are capable of developing standards that can enable companies to achieve compliance with the essential requirements of EU directives and regulations. The EU should recognize fully that standards developed by international standardization organizations that meet the requirements of the WTO TBT Agreement should be accorded “presumption of conformance” to relevant EU legislation if the technical committees developing the standards take the essential requirements of the legislation into account when they are developing the standard. This would be a major new idea and significantly benefit the U.S. and EU manufacturing industries.

On a related level, the important standards-setting bodies CEN and CENELEC are lacking in transparency and openness inasmuch as they absolutely deny full participation by any U.S.-interested party despite legitimate business concerns and impacts. This is particularly significant when there is specific knowledge that CEN/CENELEC standards resulting from mandates under EU directives will be developed into *de facto* market access requirements. Moreover, given European predominance as per the one-nation-one-vote schemes employed by the IEC and ISO, CEN/CENELEC standards inevitably have the inside track on becoming the norms adopted by these bodies. As noted above, the U.S.-EU Working Group should engage in a constructive dialogue on achieving greater reliance in both economies on international standards as defined by the WTO TBT Committee.

The U.S. and EU have been at odds for over 10 years on the subject of conformity assessment for electrical and electronic products, with the EU pushing for U.S. regulators to accept Supplier's Declaration of Conformity (SDOC). The Department of Labor (DOL) has resisted this push, with NEMA's support. As an alternative, DOL's Occupational Safety and Health Administration (OSHA) certified an EU lab to do the mandatory third-party testing and certification required by OSHA. This alternative provides market access for EU suppliers in compliance with U.S. laws and regulations to

protect workers but more importantly U.S. workplace market demand for third-party certified electrical equipment.

NEMA does not oppose SDOC. NEMA's view is that efforts to institutionalize SDOC as the only acceptable method of conformity assessment could have serious negative effects on established and successful practices in our sector. These practices have a stellar record in identifying non-compliant and counterfeit products. SDOC should be an option rather than an obligation. Where suitable monitoring institutions are in place, the market should be allowed to determine the appropriate means of conformity assessment. This final point is the key one: The market should be allowed to determine the appropriate means of conformity assessment.

In the EU market, all avenues for obtaining required third-party certification exclude U.S. testing laboratories from the final stage of product certification—the judgment of test results and approval of the product. U.S. laboratories are not allowed by EU regulators to exercise "engineering judgment" and must therefore perform redundant, additional tests that European laboratories are not required to perform. This is much different than the treatment of EU certification bodies that are permitted to continue to use best engineering practice in their testing protocols to ensure product safety. This lack of national treatment of U.S. certification bodies (in sharp contrast to the fully open, transparent and uniform process employed by OSHA in administering the Nationally Recognized Testing Laboratory (NRTL) program) significantly increases the testing costs for U.S. product manufacturers, adds increased time to market, and has effectively required U.S. certification firms to establish operations in the EU to remain competitive. Accordingly, the U.S. and EU should provide full national treatment to U.S. and EU conformity assessment (testing and certification) bodies.

Tariff Barriers

On tariffs, the U.S. and EU should vigorously pursue and secure an agreement to expand the scope of the World Trade Organization's plurilateral Information Technology Agreement to eliminate tariffs on covered equipment. In addition, the U.S. and EU should build upon their joint proposal to the WTO for an Environmental Goods and Services Agreement (EGSA) by implementing such an agreement on a bilateral basis. This could be taken several steps further in the industrial market access area by an agreement to eliminate tariffs on all U.S.-EU trade within NEMA's product scope. Most remaining tariffs fall into the "nuisance" category and thus do not perform any useful function besides some small revenue to the respective treasuries. Saving time and money not having to pay import duties could provide for notable efficiencies and re-programming of company resources into more productive activities.

Tariffs must be included within the scope of any U.S.-EU negotiations and NEMA supports complete and immediate tariff elimination.

Services

Expanding from the issue of access for conformity assessment services providers, the U.S. and EU should also use the opportunity to open to each other their markets for energy and environmental services, technical and engineering services, and maintenance and repair services.

Trade Facilitation

The U.S. and the EU should work together to develop and adopt harmonized customs classifications for traded products, especially for products where trade is growing significantly such as solid-state lighting technology. For example, the global lighting industry should not have to bear the costs of complexity and uncertainty maintained by customs authorities who should be facilitating trade of efficient and durable LED lighting products that are in increasing demand by customers.

Conclusion

In general, NEMA recommends that all U.S. free trade agreements, including any possible bilateral or regional agreement, adhere to the following principles.

- Immediate reciprocal tariff elimination
- No governmental mutual recognition agreements (MRAs) where product is not U.S. federally regulated
- National treatment
- Adequate legal and administrative infrastructure in place for implementation, transparency and enforcement of agreements
- Protection of intellectual property rights
- Elimination of technical barriers to trade (TBTs)
- Compliance with all World Trade Organization (WTO) TBT Agreement requirements
- Safe conduct of product and persons
- Energy and environmental services liberalization
- Inclusive definition of "International Standards"
- Market-driven development of product standards and conformity assessment
- Conformity attestation methods that include the optional use of the IEC Conformity Assessment Systems – IECEE, IECEX and IECQ, where appropriate

Thank you again for the opportunity to share our views and recommendations. As part of this process, we look forward to providing further advice at your request or as conditions warrant.

Respectfully,



Kyle Pitsor
Vice President, Government Relations
NEMA

US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM

REPORT ON THE USE OF VOLUNTARY STANDARDS¹ IN SUPPORT OF REGULATION IN THE UNITED STATES

(October 2009)

1. PURPOSE OF THIS REPORT

This report responds to a request by the United States-European Union (US-EU) High-Level Regulatory Cooperation Forum to provide information on the use of standards in support of regulation in the United States. The report outlines the U.S. legal and institutional framework regarding the use of standards in support of regulation. The report includes a case study from the Federal Communications Commission (FCC).

2. BACKGROUND

The Administrative Procedures Act (APA), the Trade Agreements Act of 1979 (TAA), Executive Orders and other official guidance provide a framework for regulatory agencies concerning the development and implementation of regulations. As part of this framework, agencies consider cost, enforcement mechanisms, use of voluntary consensus standards and other factors, including the avoidance of unnecessary obstacles to trade.

How these procedures and considerations are applied may also depend on statutes applicable to individual agencies. The laws and policies governing regulations reflect the fact that regulations should achieve their intended objectives, and avoid imposing burdensome or unnecessary costs. Such costs may include harm to the economy and higher prices for goods and services including through the creation of unnecessary trade barriers. The use of standards within a regulation is one aspect of a much larger analysis and decision making process that must be undertaken by a U.S. regulatory agency. Agencies are required to look at many aspects of a proposed regulation, unless directed to do otherwise by the authorizing statute, including but not limited to:

- whether a market failure or other compelling public need exists for a regulation,
- whether regulation at the Federal level is the best approach,
- the use of alternative regulatory approaches,
- how well those approaches meet an agency's regulatory objectives,
- the costs and benefits associated with a proposed regulation,
- the cost-effectiveness of a proposed regulation,
- whether to use specific standards or parts of standards, and

¹Office of Management and Budget (OMB) Circular A-119 defines the term "standard," or "technical standard" to include all of the following: (1) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices; and (2) the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.

- how the requirements contained in the regulation will be enforced.

Agencies review and analyze such issues -- both individually and collectively -- to determine the overall quality and effectiveness of the regulation.

2.1 Overview of the U.S. Regulatory Process

To better understand how the United States uses standards in regulation, it is necessary to first present a basic overview of the U.S. regulatory requirements and processes. Embedded in statutes and other documents guiding rulemaking in the United States are certain key principles, including:

- *Transparency in the making of technical assessments, factual findings, and normative policy choices, and transparent and open opportunities for public participation regarding those matters to ensure effective monitoring, critiquing and reviewing of rulemaking;*
- *Regulatory analyses, based on sound science and data and the consideration of alternative approaches to and stringency of regulation;*
- *Strong support from the government for the use of regulatory best practices; and*
- *Accountability of government agencies within the executive, legislative and judicial branches of the Federal government.*

Compliance with these principles increases the quality and effectiveness of the U.S. rulemaking process in meeting regulatory objectives, while minimizing the burden on industry and the public.

Article I, Section 1, of the Constitution gives the U.S. Congress the sole power to make statutes or laws. However, Congress has passed a number of statutes that delegate certain specified rulemaking authority to Executive Branch regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA). In so doing, Congress generally establishes factors/criteria within the statute to guide and limit how the agency exercises its use of that authority. The degree of specificity in Congress' delegation of authority and guidance varies from statute to statute. Each regulatory agency implements the authority given to it by Congress by developing and establishing regulations or rules to the extent necessary to achieve agency objectives. These regulations or rules, when finalized, have the force and effect of law. Regulations are almost always much more detailed than the statutes or laws that authorize the regulation's issuance. The statute or law containing the rulemaking authority granted by Congress to an agency is known as the agency's authorizing or "enabling" statute. An agency may have more than one enabling statute.

Congress may also supplement an agency's enabling statute(s) by later enacting new statutes or laws giving agencies other authorities or directing the regulatory agency to use its existing general rulemaking authority in a specific way to meet legitimate national objectives, such as the preservation of health and safety, animal welfare, protection of the environment, or the protection of consumer choice. In some cases, an agency's appropriation acts may also add to or limit the implementation of an agency's authorities.

All such statutes are first made publicly available in final enacted form as a Public Law. They are then codified in the United States Code, which is also publicly available. In addition, proposed and final regulations are published in the Federal Register, which is publicly available. The regulatory text in final rules is then codified in the Code of Federal Regulations, which is again publicly available.

In addition to enabling and related statutes, there are other requirements that govern the development and issuance of rules or regulations by Federal agencies. These requirements include other statutes, such as the APA, TAA, the National Technology Transfer and Advancement Act (NTAA), as well as Presidential E.O.s and Office of Management and Budget (OMB) Circulars. These requirements impose procedural obligations that are intended to ensure reasoned and fair decision making, and to ensure international trade obligations are met. These other statutes, E.O.s, and Circulars typically require that the agencies adopt regulations only after thoroughly analyzing the potential impact of the proposed regulations and considering alternative regulatory approaches. For all economically significant regulatory actions, this analysis includes an assessment and comparison of the benefits and costs of the regulation, the regulation's cost-effectiveness, an analysis of alternative regulatory approaches, and an analysis of the impact of alternative levels of stringency in the requirements contained in the regulation. These requirements are designed to ensure an open and transparent U.S. rulemaking process that gives all members of the public the opportunity to participate. The process seeks to give the public the information needed to understand what the regulatory agency is proposing to do and the rationale for its actions.

If a proposed or final regulation is likely to have a "significant" impact, that is its impact on the economy exceeding \$100 million in any one year-as defined by E.O. 12866, the agency proposing the regulation must generally submit both the proposed and final versions of the rule to the OMB for review before it is published in the Federal Register. There are some limited exceptions to this requirement. OMB reviews each economically significant regulatory proposal to ensure that it is supported by adequate regulatory analyses and is consistent with the statutes enacted by Congress and the President's priorities. Regulatory analyses undertaken by an agency for economically significant rulemakings must include an analysis of a reasonable number of regulatory alternatives. Such analyses must also include an explanation and justification as to why a particular regulatory approach was selected. Congress also requires that regulatory analyses give special attention to the impact of the proposed regulation on small businesses; small, not-for profit organizations; and U.S. State, local, and tribal governments. Certain specific burdens that will be placed on the public as the result of the regulation, such as the time and effort necessary to complete any required paperwork, energy impact, the disproportionate impacts on children, and a number of other issues also have to be considered.

2.2 Process of Rulemaking

In general, the public portion of a rulemaking begins with the publication by the agency of a Notice of Proposed Rulemaking (NPRM)² notifying the public that the Agency may adopt a

² In some cases, agencies will first issue an Advanced Notice of a Proposed Rulemaking (ANPRM) to solicit public comment and feedback on a regulatory issue to determine the need for further rulemaking. This is a particularly useful tool when an agency is considering undertaking rulemaking in a new area. The ANPRM process can also be useful when an agency wants to test out a proposal or solicit ideas before it drafts its NPRM.

specific regulation in the future and providing an opportunity for the public to comment by submitting written data, views, and arguments. The NPRM must provide sufficient information to enable the public to envision and anticipate the major aspects of the Final Rule. The NPRM typically consists of two parts: a preamble, which is a narrative discussion; and the text of the proposed regulation. The preamble informs the public of the relevant issues and considerations and may include: information on the problem to be addressed by the proposal; an explanation as to why the agency has tentatively concluded that a regulatory response is warranted; the nature of the proposed regulatory approach as well as the details about the requirements, their levels of stringency, any relevant test procedures, and the proposed use of any standards; and a description of the available research studies and empirical data on which the proposed regulation was based.

In addition, the NPRM provides instructions for submitting written comments, either electronic or hard copy, and identifies an agency contact person who can respond to questions. The agency also generally has discretion on whether to supplement the opportunity to submit written comments with an opportunity to make oral presentations at a public meeting or hearing. In some cases, agencies are required to make such an opportunity available. To the extent that the NPRM does not set forth and explain all of the factual assumptions, analyses, and methodologies that underlie the proposal, the agency will place documents addressing those matters in a public docket³ so that the public has an opportunity to read and comment on them. The agency also places all comments it receives in response to the NPRM in the public docket, with the exception of documents containing confidential business information, including trade secrets. Most Federal agencies also participate in *Regulations.gov*, an internet website that facilitates public participation in the Federal regulatory process by improving the public's ability to locate, review, and provide comment on Federal regulations.

There are *no* restrictions on who may participate in the comment process. The comment process is open to all, including individuals, businesses, and government agencies of other countries and regions. Persons wishing to comment are not subject to any governmentally controlled or sponsored selection process. Businesses and consumers decide for themselves whether to participate and may participate directly (i.e., individually), indirectly through associations and other representatives, or both. Inquiry Point operations in the U.S. Departments of Commerce and Agriculture facilitate access to the comment process by interested parties, including those in other countries.

Comments can include suggestions for the adoption of all or parts of a specific standard within the proposed regulation, as well as comments both for and against any standard or parts of a standard that the agency has proposed to incorporate into the regulation. Comments may also cover many other aspects of the proposed regulation.

The comment process serves a number of purposes, including enabling the public to:

- *Provide the agency with information, including information on standards, to enhance the agency's knowledge;*

³ A public docket is a repository for rulemaking and supporting documents (e.g., Federal Register notices, supporting analyses, and comments) for public access and comment.

- *Challenge the agency's interpretation and application of data and research, factual assumptions, analytical methodologies, tentative factual, technical, legal, and policy conclusions, practicability assessments, and assessments of the benefits and other impacts of the proposal, including those that are standard-related; and*
- *Suggest alternatives (including standards-related alternatives) to the proposed requirements and test procedures.*

The agency must then consider the data, views, and arguments submitted by the public, including any substantive comments related to the use and content of standards that may be incorporated into the regulation. In issuing any Final Rules (the revised version of a proposed regulation which will be binding on the public when effective), the agency must provide a statement of the rule's basis and purpose and include the agency's discussion of and response to the public comments, which again includes those that are standards-related. Although many of the analytic requirements for rulemakings are established by Executive Order and other Executive Branch guidance, some of the requirements of a final rule have developed from case law, such as the obligation of agencies to adequately respond to significant comments and to provide a reasonable basis for the regulatory approach that the agencies has chosen and therefore may be challenged in court. It should be noted that there are exceptions to this process in cases where emergency rulemaking is necessary.

3. POLICY AND LEGAL CONTEXT FOR THE USE OF STANDARDS IN SUPPORT OF REGULATIONS/ PROCUREMENT

3.1 Obligations at the National Level

The U.S. Federal regulatory system, described above, is designed to protect and improve the health, safety, and well being of U.S. citizens and to protect the environment. It seeks to improve the effectiveness of regulation without imposing unacceptable or unreasonable costs on society. U.S. regulatory policies recognize that marketplace forces are generally the best engine for driving economic growth. U.S. regulatory policies emphasize that regulations should be cost-effective, consistent, sensible, and understandable, and that the regulatory process should be open, transparent and fair to all interested parties. Consistent with this philosophy and to codify a long standing practice by Federal agencies, the U.S. Congress enacted *Public Law 104-113*, also known as the *National Technology Transfer and Advancement Act* (NTTAA), in March 1996.⁴ The NTTAA and the Trade Agreements Act of 1979, as amended (TAA)⁵ are two key pieces of U.S. legislation affecting the regulatory and procurement use of standards. The NTTAA directs federal agencies to use, when practical and not otherwise prohibited by law, standards developed by voluntary consensus standards bodies to achieve public policy and procurement objectives, and the TAA prohibits federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade and requires federal agencies to take into consideration international standards.

⁴ A copy of the entire text of the law is available at: http://standards.gov/standards_gov/nttaa.cfm.

⁵ The standards-related provisions of the TAA are codified at United States Code, Title 19, Chapter 13, Subchapter II, Technical Barriers to Trade (Standards).

The NTTAA directs U.S. Federal agencies on their use of standards developed by voluntary consensus standards bodies for both regulatory and procurement purposes. It instructs U.S. Federal agencies to use voluntary consensus standards wherever practical, in lieu of creating government-unique standards. In addition, the Act instructs agencies to review their development and promulgation of conformity assessment requirements and measures with the goal of eliminating unnecessary duplication and complexity in such requirements. The Act also charges the National Institute of Standards and Technology (NIST)⁶ with coordinating the standards needs of U.S. Federal agencies to achieve greater reliance on voluntary consensus standards.

Further guidance on implementing the NTTAA is contained in the Office of Management and Budget's (OMB) Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.⁷ This Circular instructs agencies to use voluntary consensus standards in lieu of government-unique standards, except where such usage is inconsistent with law or otherwise impractical. It defines "voluntary consensus standards" as standards developed or adopted by a voluntary consensus body. It also defines a "voluntary consensus body" as an organization – whether domiciled in the United States or elsewhere – that has the following attributes: openness, balance of interests, due process, an appeals process, and consensus. The Circular also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The aim of the Circular is minimize agency reliance on government-unique standards.

The law and the Circular also recognize that participation in voluntary standards development can benefit agencies in a wide range of activities. U.S. agencies and departments, including regulatory agencies, participate in the development of domestic and international standards as one means of helping to achieve specific goals and missions through cooperative efforts in a wide range of health, safety, environmental, technical and other areas. The Circular directs agencies to consult with voluntary consensus standards bodies, both domestic and international, and to participate with such bodies in the development of voluntary consensus standards when consultation and participation is in the public interest and is compatible with the agencies' missions, authorities, priorities, and budget resources. Such participation also is carried out in accordance with other applicable policies and laws as well as international agreements such as the WTO Agreement on Technical Barriers to Trade (TBT).

The TAA implements U.S. obligations under the TBT Agreement regarding the development, adoption, and application of technical regulations, standards, and conformity assessment procedures. Specifically, the TAA prohibits Federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade. It further directs Federal agencies to ensure non-discriminatory treatment in applying standards-related activities to any imported product. The TAA directs each Federal agency to use performance based requirements, if appropriate; to take into consideration international standards; and, if appropriate, to base technical regulations on international standards. Further, the TAA

⁶ The National Institute of Standards and Technology (NIST) is an agency with the U.S. Department of Commerce.

⁷ A copy of the entire text of OMB Circular A-119 is available at: http://standards.gov/standards_gov/a119.cfm.

provides an illustrative list of reasons that it may not be appropriate to base a technical regulation on an international standard.

There are also other policies and statutes that direct agencies to rely on voluntary consensus standards and avoid use of government-unique standards. For example, such policies and statutes include:⁸

- *The Consumer Product Safety Act, which directs the Consumer Product Safety Commission to rely on voluntary consensus consumer product safety standards rather than promulgate its own standards;*
- *The Telecommunications Act of 1996, which contains several provisions that encourage Federal Communications Commission (FCC) reliance on private sector standards;*
- *The Food and Drug Administration (FDA) Modernization Act of 1997, which contains provisions that allow the FDA in some instances to accept attestation to certain standards during the evaluation of premarket submissions for electrical medical devices; and*
- *MILSPEC Reform, which has resulted in the Department of Defense's (DoD's) moving away from unique specifications and standards (MILSPECS) and toward reliance on private sector standards.*

These Acts of Congress and executive branch policies set forth requirements and goals regarding Federal usage of standards.

3.2 Stakeholder Participation in the Regulatory Use of Standards

In accordance with the NTTAA, the TAA, and U.S. international obligations, U.S. regulators (in considering what standards to use in regulations) look to standards that have been developed in accordance with certain principles. These principles include: transparency, openness, impartiality/balance and consensus. Most standards developers within the U.S. standards system endorse the principles of openness, balance, and lack of dominance in the standards development activities.⁹ Standards developed in accordance with such principles

⁸ Based on information compiled by the *American National Standards Institute (ANSI)*, "Significant Federal Laws and Policies," http://www.ansi.org/government_affairs/laws_policies/laws.aspx?menuid=6

⁹ The American National Standards Institute (ANSI) has established a process to approve standards as "ANS" standards. ANS standards must have been developed in accordance with the following principles:

- *Openness* means that participation in a standards development activity is open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation, and voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.
- *Lack of dominance* means that the standards development process is not to be dominated by any single interest category, individual or organization. This applies to government agencies that choose to participate in a standards development process. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.
- *Balance* means that standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance.

allow any interested party or stakeholder, whether or not based in the United States, to participate as an equal member in the standards development process and to have his or her viewpoint fairly considered. A representative from one or more government agencies may participate and have his or her viewpoint(s) heard, but such viewpoints do not carry more weight than those of other stakeholders in the process. In other words, agency representatives are not to dominate the process.

Thus, during the standards development process, stakeholders have the opportunity to influence the content of any standard developed by bodies that adhere to these principles, including standards that might be used in regulatory applications. During the rulemaking process, stakeholders have a second opportunity to influence the choice of standard or parts of a standard that a regulatory agency may be considering for adoption. As noted above, the U.S. rulemaking process is committed to transparency in the development of technical assessments, factual findings, and normative policy choices. It is also committed to transparency and openness in the public participation process regarding those matters to ensure effective monitoring, critiquing and reviewing of the rulemaking process.

4. IMPLEMENTATION

4.1 Implementation of Legislation and Policies

As mentioned above, OMB Circular A-119 provides support for the implementation of the NTTAA. The Circular contains guidance for Federal agencies and sets forth policies on Federal use of and participation in the development of voluntary consensus standards and on conformity assessment activities. NIST is charged with carrying out the responsibility of the Secretary of Commerce to coordinate, foster and otherwise implement the provisions of the Circular within the Executive Branch of the U.S. government. NIST provides administrative guidance and assistance to other Federal agencies, including identifying voluntary consensus standards and conformity assessment bodies that support agencies' missions. The TAA gives the United States Trade Representative (USTR) the lead role within the Federal government on the coordination and development of international trade policy related to implementation of the standards-related provisions of the Act. The TAA also gives USTR the responsibility for coordinating discussions and negotiations with foreign countries for the purpose of establishing mutual arrangements with respect to standards-related activities. Coordination under the NTTAA and the TAA is conducted through two interagency committees.

The Interagency Committee on Standards Policy (ICSP) is charged with providing consistent and effective standards policies across government. The ICSP was authorized by OMB Circular A-119 and is chaired by NIST. The ICSP provides advice and recommendations to the Secretary of Commerce and other Executive Branch agencies on matters related to Federal standards policy. Besides promoting effective and consistent standards policies, the ICSP fosters cooperation between government, industry, and other private organizations involved in

In addition, public and private sectors joined together under ANSI auspices and published the United States Standards Strategy (USSS) in 2005. The Strategy confirms the U.S. commitment to these and other internationally accepted principles of standardization endorsed by the World Trade Organization (WTO) – transparency, openness, impartiality, effectiveness and relevance, consensus, performance-based, coherence, due process, and technical assistance. A copy of the USSS is available at: http://www.ansi.org/standards_activities/nss/uss.aspx?menuid=3

standards activities. The ICSP also seeks furtherance of U.S. domestic and foreign goals, and, to this end, fosters cooperative participation by the Federal government and U.S. industry and other private organizations in standards activities. This includes the related activities of sampling, inspection and testing; management system registration; certification; and accreditation. The ICSP meets three to four times a year and is composed of Federal agency standards executives or their designated representatives.

To ensure that agencies are following the provisions of the NTTAA and the Circular, Federal agencies must annually report to NIST on: their participation in standards development organizations and conformity assessment activities; their adoption and use of voluntary standards; and on the promulgation of any government-unique standards, along with agencies' rationales for such use. This results in an annual review of the standards activities of the U.S. government. NIST files annual summary reports with the OMB, which are sent to Congress. Individual agency reports and the annual summary reports to OMB and Congress are available at Standards.gov, a NIST-supported web portal for government standards activities.

Meanwhile, USTR oversees an interagency trade policy process that incorporates input from numerous government agencies, including regulatory agencies, in the implementation and coordination of U.S. trade policy.¹⁰ The vast majority of decision-making on standards-related activities takes place at the Trade Policy Staff Committee (TPSC) Subcommittee on Technical Barriers to Trade. In cooperation and coordination with relevant agencies, including regulatory agencies, the USTR monitors U.S. compliance with WTO and any other international obligations related to technical regulations, standards, and conformity assessment procedures, including those associated with the use of international and performance-based standards.

As noted previously, agencies are required to use relevant international standards to the extent provided in Article 2.4 of the WTO TBT Agreement and other trade agreements, as a basis for their technical regulations. However, agencies are not prevented from taking measures at levels the agencies consider necessary for the protection of human, animal, plant life or health, and the environment; or for the prevention of deceptive practices. International standards can be used by regulatory agencies to meet these objectives. The policy of the U.S. government is to use the term "international standard" to refer those standards developed in a manner that is consistent with the World Trade Organization (WTO) Technical Barrier to Trade (TBT) Committee's *Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement*.¹¹

All economically significant government regulations require the preparation of a detailed Regulatory Impact Analysis (Presidential Executive Order (E.O.) 12866).¹² According to

¹⁰ The interagency coordination process among U.S. Federal agencies related to good regulatory practice is described in detail in the Communication from the United States to the WTO Committee on Technical Barriers to Trade, "Good Regulatory Practice: The Role of Strong Central Government Coordination in TBT Agreement Implementation," G/TBT/W/315.

¹¹ See Annex B of G/TBT/1/Rev.9.

¹² For a copy of E.O. 12866, see <http://www.whitehouse.gov/omb/inforeg/eo12866.pdf>.

OMB Circular A-4, which provides more detail on how to conduct a proper Regulatory Impact Analysis (RIA), the agency should carefully analyze any concerns that their rulemaking could create a non-tariff barrier. Although Circular A-4 does not specifically require it, many agencies do consider the costs and benefits of using international standards as a part of their analyses. In fact, an OMB-EC joint report on considering the international impacts of regulation recommended that agencies should consider existing international standards or regulatory approaches as an explicit regulatory alternative in an RIA. OMB encourages such analysis of standards under Circular A-4, concluding that such analysis would satisfy an agency's obligation to consider standards under OMB Circular A-119 and the NTTAA. In addition, as noted above, the TAA requires Federal agencies to take into consideration international standards and to base an agency's requirements on international standards where appropriate.

For example, on November 23, 2005, the U.S. Federal Aviation Administration (FAA) published a Notice of Proposed Rulemaking (NPRM) in the Federal Register entitled "Reduction of Fuel Tank Flammability in Transport Category Airplanes." This NPRM was designed to alleviate a risk that had led to several fatal airplane accidents caused by fuel tank explosions, including the Boeing 747 TWA Flight 800 explosion off Long Island, New York in 1996. The FAA proposed new rules that would require operators and manufacturers of all transport-category airplanes in operation in the United States, including airplanes manufactured by Airbus, to take steps to prevent electrical and other systems from igniting flammable vapors in the fuel tank. In its analysis of the impact of the proposal, the FAA specifically noted that the FAA had also considered the interaction of this rulemaking with international standards. Specifically, in keeping with U.S. obligations under the Convention on International Civil Aviation, FAA's policy was to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined for purposes of the proposed rulemaking that there were no applicable ICAO Standards and Recommended Practices.

On August 23, 2007, the U.S. Customs and Border Protection (CBP) of the Department of Homeland Security (DHS) published a final rule in the Federal Register entitled "Advance Electronic Transmission of Passenger and Crew Member Manifests for Commercial Aircraft and Vessels." This final rule required electronic manifest transmission to CBP of passenger and crew member information for those onboard international commercial flights and voyages to and from the United States. The rule noted that CBP policies allowed data transmission under this rule to follow the UN/EDIFACT (United Nations/Electrical Data Interchange for Administration, Commerce, and Trade), an international electronic data interchange standard developed under the auspices of the United Nations.

Standards are also a key element of the Coast Guard's strategic plan for maritime regulatory reform. The U.S. Coast Guard has stated that "The Office of Marine Safety, Security, and Environmental Protection is committed to developing nationally and internationally recognized standards as a means to improve maritime safety and marine environmental protection, and to promote an internationally competitive U.S. maritime industry." However, the U.S. Coast Guard also recognizes that safety must be cost-effective. In 1995 the Coast Guard began an effort to look at its regulations, eliminate those that were outdated or inefficient, and adopt international standards where possible. As an example of the Coast Guard's effort, in 1996 the Coast Guard revised its electrical regulations adopting 86 new standards including 32 standards developed by the International Electrotechnical Commission

(IEC). To date, the Coast Guard has adopted approximately 450 industry standards, saving over 25,000 pages of federal regulations and the associated regulation maintenance, while specifying standards already familiar to the regulated industry.

In addition to often examining the possibility of using international standards within a regulation during the analysis of the proposed regulation's impact, agencies *must* consider and respond to substantive comments made during the rulemaking process (including comments on the use or non-use of international standards) and justify their final decision in that regard before publishing a final rule.

Some agencies, such as the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA), also participate in a number of international forums. PHMSA is involved in an ongoing process of harmonizing the U.S. Hazardous Materials Regulations (HMR) with international standards and regulations. Participation helps ensure that U.S. interests are communicated and considered in the development of such international standards. PHMSA's objective is to establish and maintain a global regulatory system for hazardous materials transportation that will enhance the safe, secure, and efficient movement of hazardous materials.

In addition, E.O. 12866 specifically addresses the use of performance-based standards, informing agencies that:

"... (P)erformance standards are generally to be preferred to engineering or design standards because performance standards provide the regulated parties the flexibility to achieve the regulatory objective in a more cost-effective way. It is therefore misleading and inappropriate to characterize a standard as a performance standard if it is set so that there is only one feasible way to meet it; as a practical matter, such a standard is a design standard. In general, a performance standard should be preferred wherever that performance can be measured or reasonably imputed. Performance standards should be applied with a scope appropriate to the problem the regulation seeks to address. For example, to create the greatest opportunities for the regulated parties to achieve cost savings while meeting the regulatory objective, compliance with air emission standards can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable air quality outcomes (such as "hot spots" from local pollution concentration)."

4.2 Mechanisms and Methods to Make Use of Standards

The U.S. standards system is primarily voluntary, private sector, and marketplace driven with multiple standards developers taking an active role. The U.S. Federal government participates as one of many stakeholders in the standards development process, not as the driver of the process. By comparison, governments in other nations play a more active role; and the process is more centralized.

Although not a driver of the process, as noted above, the U.S. government is committed to reliance on voluntary standards for procurement and regulation, where such usage is consistent with regulatory and procurement objectives. Government regulatory agencies use externally developed standards in a wide variety of ways, including the following:

- *Incorporation by Reference:* An agency may adopt a voluntary standard without change by incorporating the standard in an agency's regulation or by listing (or referencing) the standard by title. For example, the Occupational Safety and Health Administration (OSHA) adopted the National Electrical Code (NEC) by incorporating it into its regulations by reference.
- *Strong Deference:* An agency may grant strong deference to standards developed by a particular organization for a specific purpose. The agency will then use the standards in its regulatory program unless someone demonstrates to the agency why it should not.
- *Basis for Rulemaking:* The agency reviews a standard, makes appropriate changes, and then publishes the revision in the Federal Register as a proposed regulation. Substantive comments received from the public during the rulemaking proceeding may result in changes to the proposed rule before it is issued as a final rule.
- *Regulatory Guidance:* An agency may permit adherence to a specific standard as an acceptable, though not compulsory, way of complying with a regulation. The agency provides in the rule text that a regulated entity may comply with the rule set out in the text or may comply with a referenced voluntary standard.
- *Guidelines:* An agency may use standards as guidelines for complying with general requirements. The guidelines are advisory only and therefore compliance with them is not mandatory.
- *Deference in Lieu of Developing a Mandatory Standard:* An agency may decide that it does not need to issue a mandatory regulation because voluntary compliance with either an existing standard or one developed for the purpose will suffice in meeting the needs of the agency.

A regulatory agency's approach to the use of standards in a particular application is based on the statutes under which the rulemaking is proceeding; the nature of the public comments received; and often the costs, benefits and cost-effectiveness of the various approaches to such usage.

Guidance on the use of voluntary standards in procurement applications may be found in the General Services Administration's Federal Standardization Manual.¹³ The manual notes that when a government agency is in the initial stages of developing a Federal Product Description (FPD)¹⁴, the use of voluntary standards are to be given preference over the development of government unique FPDs. The agency is required to do extensive research to determine if a voluntary standard exists that will satisfy its needs and is consistent with applicable laws and regulations. If an existing voluntary standard will satisfy the agency's needs, the agency must adopt the standard by one of the following processes:

- Either the procedure must satisfy the adoption requirement established in OMB Circular A-119, or
- The agency may formally adopt the standard in whole and issue an adoption notice, or

¹³ For a copy of this manual, see http://www.dsp.dla.mil/APP_UIL/content/policy/docs/fsman.pdf

¹⁴ Federal Product Descriptions or FPDs consist of Federal specifications and related Federal qualified products lists, Federal standards, and commercial item descriptions (CIDs).

- The agency may reference the voluntary standard in whole or in part in its procurement documents or regulations.

It is also the U.S. Department of Defense's (DoD) policy to make maximum use of non-Government standards and commercial technologies, products, and practices.¹⁵ DoD is committed to the adoption and use of voluntary consensus standards (defined in DoD 4120.24-M as "non-Government standards") where practical, instead of developing new or updating existing government specifications and standards. This policy is consistent with P.L. 104-113, the NTTAA and with OMB Circular A-119.

In addition, the U.S. government, as represented by DoD, is a member of the North Atlantic Treaty Organization (NATO) and endorses the NATO Policy for Standardization that emphasizes the adoption of suitable civil standards (or non-government standards) for use within NATO. The NATO Committee for Standardization (NCS) has issued the NATO Framework Document on Civil Standards, which describes the Alliance's role with respect to relations with Civil Standards Bodies (private sector standards bodies), to make best use of civil standards within the full range of NATO tasks. The document provides that, whenever possible and where advantageous, NATO members use the most appropriate and openly available civil standards, rather than develop military standards. It also stresses that NATO should only develop its own standards when no suitable civil standards exist.

5. MAINTAINING AND UPDATING STANDARDS

5.1 Agency Participation in and Knowledge of Standards Development

Within budgetary constraints, regulatory agencies are encouraged to participate in standards development activities that are consistent with their mission. Such participation is designed to keep agencies aware of standards under development or revision, as well as to contribute to the development of standards that will eliminate the need for government unique standards to be used in regulatory applications.

In the procurement area, the GSA Federal Standardization Manual directs Federal agencies to participate in activities of voluntary standard bodies, where participation has been determined to be beneficial to the agency. The government agency is to participate in a voluntary standard body when participation is in the public interest and is compatible with agency's mission, authorities, priorities and budget limitations. The manual notes that the benefits of such participation include:

- *Allowing agencies to stay abreast of new technologies;*
- *Reducing the cost to the Federal government of developing government unique standards;*
- *Providing agencies with opportunities to learn from both manufacturers and end users; and*

¹⁵ For Information on the U.S. Department of Defense's Standardization policy, see: http://www.dsp.dla.mil/APP_UIL/policy.aspx?action=content&accounttype=displaypolicy&contentid=79#GSA

- *Encouraging reliance on the private sector to supply government's needs for goods and services.*

Agencies also have access to a number of sources for standards-related information, including standards libraries and the services of NIST's National Center for Standards and Certification Information (NCSCI) that can provide agencies with information regarding potential standards that may be of interest in a regulatory or procurement action.

Regulatory agencies may also receive information on standards that may be appropriate or inappropriate for regulatory use during the extensive public comment process that most proposed regulations must undergo.

5.2 Maintenance, Updating and Revision of Standards Used in Regulation

The U.S. regulatory process, while very open and transparent, is also resource intensive. Agencies are not only required to involve the public when rules are developed and issued, they are also required to involve the public in amendments, revisions, or repeals of such rules. To ensure that the public is informed, agencies are generally required to publish proposed and final rules in the *Federal Register*. They are also required to publish amendments, revisions or repeals of such rules in the *Federal Register*, including changes to rules that are designed to incorporate a new or revised edition of a standard.

Standards referenced in regulations are generally required to include the title, date, edition, author, publisher, and identification number of the publication. Future amendments or revisions of standards that are incorporated by reference do not automatically amend the requirements of a regulation. Agencies that wish to update a standard that is referenced within a regulation must generally undertake another rulemaking process. Because rulemaking resources are often limited, updating references to standards that have been amended or revised is often not a high priority, particularly if the version currently referenced in the regulation still meets the agency's regulatory objectives.

Many agencies have been actively exploring the use of methods to speed the process of updating references to standards included within regulations, and some creative solutions have been undertaken to speed the rulemaking process in specific cases. For example, some agencies have adopted small, non-controversial revisions to standards through a "direct" final rule. Such a rulemaking stage is not preceded by a proposed rule. However, it includes a public comment period on the implementation of the direct final rule. An agency is obligated to withdraw the direct final rule and proceed with the normal proposed rulemaking process if it receives any adverse comment to the direct final rulemaking process. This is just one example. To date, no one-size-fits-all solution to this issue has been developed.

Currency is less of a problem in the procurement area. The General Services Administration's Federal Standardization Manual¹⁶ requires that agencies not cite the issue date of a standard in the FPD when referencing the voluntary standard, unless a specific issue of the voluntary standard is needed.

¹⁶ For a copy of this manual, see http://www.dsp.dla.mil/APP_UIL/content/policy/docs/fsman.pdf

5.3 Normative References Included in Standards Used in Regulation and Procurement

Currency, as well as applicability, are also issues associated with normative references that are contained in standards that have been incorporated into regulations or included within procurement requirements. A number of private sector, voluntary, consensus standards, including those published by the International Organization for Standardization (ISO), contain a section that lists one or more additional standards that are deemed to be “Normative References.” “Normative references” are defined by ISO and the American National Standards Institute (ANSI) as being “indispensable for the application of the document” or standard in which they are listed. Standards referenced in both regulations and in procurement documents may contain a list of “normative references.”

CASE STUDY EXAMPLE

CASE STUDY: Federal Communications Commission

The U.S. Federal Communications Commission (FCC), a United States government agency established by the Communications Act of 1934, regulates interstate and international communications by radio, television, wire, satellite and cable. The FCC's jurisdiction covers the 50 States, the District of Columbia, and U.S. possessions.

The FCC regulates the private sector communications industry by establishing technical regulations found in Volume 47 of the Code of Federal Regulations (C.F.R.) Parts 0 to 101.¹⁷ These technical regulations aim at minimizing the potential of causing harmful interference to radio services from transmitters and other equipment.

There are a number of ways that the FCC uses standards in support of the technical regulations and conformity assessment procedures. The FCC provides for the use of standards as follows:

- Incorporation by reference;
- Measurement procedures published by national engineering societies;
- Reference to technical limits in a standard; and
- Technical criteria established by standards development organizations.

Incorporation by reference was established by statute and allows Federal agencies to publish regulations in the Federal Register by referring to materials already published elsewhere. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register. The FCC has incorporated by reference standards developed by the following standards development organizations:

- Advanced Television Systems Committee (ATSC)
- American Society for Testing Materials (ASTM)
- Consumer Electronics Association (CEA)
- Electronic Industry Association (EIA)
- Federal Aviation Administration (FAA)

¹⁷ 47 C.F.R. §§ 0 – 101.

- International Electrotechnical Commission (IEC)
- International Maritime Organization (IMO)
- International Radio Consultative Committee (IRC)
- International Organization for Standardization (ISO)
- International Special Committee on Radio Interference (CISPR)
- International Telecommunication Union (ITU)
- International Telegraph and Telephone Consultative Committee (CCITT)
- North American Numbering Council (NANC)
- Radio Technical Commission for Aeronautics (RTCA)
- Radio Technical Commission for Maritime Services (RCTM)
- Society of Cable Telecommunications Engineers (SCTE)
- Telecommunications Industry Association (TIA)

Measurement Procedures – Several measurement procedures have been identified in the FCC regulations by incorporation by reference. In addition to measurement procedures identified by the FCC, the rules provide flexibility to use standards developed by standards development organizations. Those measurement procedures found to be acceptable by the FCC may be used to demonstrate compliance with the technical regulations.

Reference to technical limits in a standard – For example, the technical requirements for digital devices found in §15.107 have harmonized the conducted emission requirements with the international standards found in CISPR 22.¹⁸ In §15.109, the FCC rules allow equipment to comply with the radiated emission limits in CISPR 22, third edition, as an alternative to the limits given in FCC Part 15.¹⁹

Technical Criteria established by standards development organizations – For example, the FCC created the Administrative Council for Terminal Attachment (ACTA), which is sponsored by the Telecommunications Industry Association (TIA) and the Alliance for Telecommunications Industry Solutions (ATIS).²⁰ Standards development organizations (SDO) accredited by ANSI may establish technical criteria for terminal equipment pursuant to ANSI consensus decision making procedures and submit such criteria to ACTA.

Conformity Assessment Procedures

The FCC administers an authorization program to ensure that equipment reaching the market complies with the technical requirements in the rules. The FCC uses three different equipment authorization procedures, depending on the type of equipment, as specified in the rules. The procedure applicable to a particular device depends on the risk of interference that the device poses to licensed radio services. The three equipment authorization procedures are as follows:²¹

¹⁸ See *Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement, International Electrotechnical Commission (IEC), International Special Committee on Radio Interference (CISPR), Publication 22.*

¹⁹ 47 C.F.R. § 15.109.

²⁰ 47 C.F.R. § 68.602.

²¹ 47 C.F.R. § 2.907.

Verification is a self-approval procedure whereby the responsible party makes measurements or takes the necessary steps to ensure that the equipment complies with the appropriate technical standards.²² Examples of devices subject to Verification include business Class A computer equipment, Television (TV) and Frequency Modulated (FM) receivers, and non-consumer Industrial, Scientific and Medical (ISM) equipment.

Declaration of Conformity (DoC) is a manufacturer's self-approval procedure where the responsible party (who could be the manufacturer, the grantee or the importer of the equipment) makes measurements at a recognized accredited test laboratory to ensure that the equipment complies with the appropriate technical standards. A test lab must be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) or the American Association of Laboratory Accreditation (A2LA); or be a designated accredited laboratory under the terms of a negotiated Mutual Recognition Agreement (MRA).²³ The testing laboratory is required to be accredited to the international standard ISO/IEC Guide 17025.²⁴ Devices subject to DoC must be properly labelled in accordance with FCC Rules.²⁵ Examples of devices subject to DoC include: certain personal computers and peripherals; Citizen Band (CB) receivers; super-regenerative receivers; TV interface devices; and consumer ISM equipment.

Certification is an equipment authorization issued by the FCC or its designated entities based on representations and test data submitted by the applicant. Third party certification bodies, accredited to ISO/IEC Guide 65, may be recognized by the FCC to perform the certification of equipment.²⁶ The FCC is notified when products are certified. A complete copy of the application for certification is maintained in the FCC database. Examples of devices subject to certification include: high power transmitters operating in Licensed Radio Services; low power transmitters, such as cordless telephones; garage door opener controllers; radio control toys; security alarm systems; and scanning receivers. Personal computers and peripherals; super-regenerative receivers; and TV interface devices, such as video cassette recorders (VCR), may show compliance with the FCC rules by using either certification or DoC equipment authorization procedures.

Requirements for Digital Devices

The use of digital technologies has become very common in the design of electronic equipment. Such equipment is known as digital devices and is classified by the FCC as unintentional radiators.²⁷ Digital devices have the potential for causing interference with

²² 47 C.F.R. § 2.909.

²³ 47 C.F.R. §§ 2.1071 - 2.1077.

²⁴ See *General Requirements for the Competence of Testing and Calibration Laboratories*, International Standards Organization (ISO) International Electrotechnical Commission (IEC), ISO/IEC 17025:2005.

²⁵ 47 C.F.R. § 15.19.

²⁶ See *General Requirements for Bodies Operating Product Certification Systems*, ISO/IEC 65:1996.

²⁷ An unintentional radiator is defined in the FCC rules as a device that intentionally generates radio frequency energy for use within the device, or that sends radio frequency signals by conduction to associated equipment via connecting wiring, but which is not intended to emit RF energy by radiation or induction. See 47 C.F.R. § 15.3(z).

licensed radio services and are subject to the technical regulations in FCC Part 15. Examples of such devices include: personal computers, calculators, digital cameras, telephones and similar electronic devices.

Technical requirements – For digital devices, there are two major requirements: conducted and radiated emissions. The FCC has harmonized the conducted emission requirements with the international standards found in CISPR 22. For radiated emissions, the FCC rules allow equipment to comply with the radiated emission limits in CISPR 22, third edition, as an alternative to the limits given in FCC Part 15.²⁸ Since CISPR 22 does not provide limits for radiated emissions above 6 GHz, it is necessary for a digital device to also comply with the FCC limits at these frequencies.

Measurement procedures – Measurement procedures for digital devices have been developed by the ANSI Accredited Standards Committee, C63®. Digital devices are required to be tested to the measurement procedures found in C63.4-2003.²⁹ This standard is specified in the FCC rules by incorporation by reference.³⁰

Conformity Assessment – A digital device such as a personal computer is required to demonstrate compliance with the FCC rules by use of the Declaration of Conformity procedures. Testing is to be performed by a recognized testing laboratory that has been accredited to ISO/IEC Guide 17025.³¹

²⁸ 47 C.F.R. § 15.109.

²⁹ See *American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz*, IEEE C63.4-2003.

³⁰ 47 C.F.R. § 15.31.

³¹ 47 C.F.R. § 2.948.

EU LEGISLATION MAKING USE OF VOLUNTARY STANDARDS

I. EU legislation following the New Approach method

TITLES OF DIRECTIVES	OFFICIAL JOURNAL	AS LAST AMENDED BY
Low voltage : Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to Electrical Equipment designed for use within certain voltage limits	OJ L 374; 27.12.2006, p. 10-19	--
Simple pressure vessels : Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels	OJ L 220; 08.08.1987; p. 48-59	Council Directive 93/68/EC; OJ L 220, 30.08.1993; p. 1-22
Toys : Council Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 relating to the safety of toys	OJ L 170, 30.06.2009; p. 1	--
Construction products : Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products	OJ L 40; 11.02.1989; p. 12-26	Council Directive 93/68/EC; OJ L 220, 30.08.1993; p. 1-22
Electromagnetic compatibility : Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC Text with EEA	OJ L 390; 31.12.2004; p. 24-37	--

<u>Machinery :</u> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (Text with EEA relevance)	OJ L 157; 09.06.2006; p. 24-86	---
<u>Personal protective equipment :</u> Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment	OJ L 399; 30.12.1989; p. 18-38	Directive 96/58/EC OJ L 236, 18.09.1996; p. 44
<u>Non-automatic weighing instruments :</u> Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments	OJ L 189; 20.07.1990; p. 1-16	Council Directive 93/68/EC; OJ L 220, 30.08.1993; p. 1-22
<u>Active implantable medical devices :</u> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices	OJ L 189; 20.07.1990; p. 17-36	Directive 2007/47/EC; OJ L 247, 21.09.2007; p. 21-55
<u>Appliances burning gaseous fuels :</u> Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels	OJ L 196; 26.07.1990; p. 15-29	Council Directive 93/68/EC; OJ L 220, 30.08.1993; p. 1-22
<u>Efficiency Requirements for new hot-water boilers fired with liquid or gaseous fuels :</u> Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	OJ L 167; 22.06.1992; p. 17-28	Council Directive 2005/32/EC; OJ L 191; 22.07.2005; p. 29-58
<u>Explosives for civil uses :</u> Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses	OJ L 121; 15.05.1993; p. 20-36	Commission Directive 2008/43/EC; OJ L 94, 05.04.2008; p. 08-12
<u>Medical devices :</u> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	OJ L 169; 12.07.1993; p. 1-43	Directive 2007/47/EC; OJ L 247, 21.09.2007; p. 21-55

<u>Equipment explosive atmospheres (ATEX) :</u> Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres	OJ L 100; 19.04.1994; p. 1-29	---
<u>Recreational craft :</u> Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft	OJ L 164; 30.06.1994; p. 15	Directive 2003/44/EC; OJ L 214; 26.08.2003; p. 18-35
<u>Lifts :</u> Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts	OJ L 213; 07.09.1995; p. 1-31	--
<u>Pressure equipment :</u> Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment	OJ L 181; 09.07.1997; p. 1-55	--
<u>In vitro diagnostic medical devices :</u> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices	OJ L 331; 07.12.1998; p. 1-37	--
<u>Radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity :</u> Directive 1999/5 of the European Parliament and of the Council on Radio Equipment and Telecommunications Terminal Equipment and the mutual recognition of their conformity	OJ No L 91; 07.04.1999; p. 10-28	--
<u>Cableway installations designed to carry passengers :</u> Directive 2000/9/EC of the European Parliament and the Council of 20 March 2000 relating to cableway installations designed to carry passengers	OJ L 106; 03.05.2000; p. 21-48	--

Measuring instruments : Directive 2004/22/EC of the European Parliament and the Council of 31 March 2004 on measuring instruments; Text with EEA relevance	OJ L 135; 30.04.2004; p. 1-80	--
Eco-design of energy-using products : Directive 2005/32/EC of the European Parliament and the Council of 6 July 2005 establishing a framework for the setting of ecodesign requirements for energy-using products and amending Council Directive 92/42/EEC and Directives 96/57/EC and 2000/55/EC of the European Parliament and of the Council	OJ L 191, 22.7.2005, p. 29	--
Pyrotechnic articles : Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles	OJ L 154, 14.6.2007, p. 1	---

II. Other EU legislation relying on the use of voluntary standards

Packaging and packaging waste : Directive 94/62/EC of the European Parliament and the Council of 20 December 1994 on packaging and packaging waste	OJ L 365; 31.12.1994; p. 10-23	Directive 2005/20/EC; OJ L 70; 16.03.2005; p. 17-18
Interoperability of trans-European high-speed rail system : Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system	OJ L 235; 17.09.1996; p. 6-24	Directive 2004/50/EC; OJ L 164; 30.04.2004; p. 114-163
Interoperability of trans-European conventional rail system : Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system	OJ L 110; 20.04.2001; p. 1-27	Directive 2004/50/EC; OJ L 164; 30.04.2004; p. 114-163
Marine equipment : Council Directive 96/98/EC of 20 December 1996 on Marine Equipment	OJ L 46; 17.02.1997; p. 25-56	Directive 2002/84/EC; OJ L 324; 29.11.2002; p. 53-58

<u>Energy efficiency requirements for household electrical refrigerators, freezers and combinations thereof :</u> Directive 96/57/EC of the European Parliament and of the Council of 3 September 1996 on energy efficiency requirements for household electric refrigerators, freezers and combinations thereof	OJ L 236; 18.09.1996; p. 36-43	--
<u>Transportable pressure equipment :</u> Council Directive 1999/36/EC of 29 April 1999 on transportable pressure equipment	OJ L 138; 01.06.1999; p. 20-56	--
<u>Noise emission in the environment by equipment for use outdoors :</u> Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors	OJ L 162; 03.07.2000; p.1-78	--
<u>Energy efficiency requirements for ballasts for fluorescent lighting :</u> Directive 2000/55/EC of the European Parliament and of the Council of 18 September 2000 on energy efficiency requirements for ballasts for fluorescent lighting	OJ L 279; 01.11.2000; p. 33-39	---
<u>Airborne noise emitted by household appliances :</u> Council Directive 86/594/EEC of 1 December 1986 on airborne noise emitted by household appliances	OJ No L 344; 06.12.1986; p. 24-27	---
<u>General product safety :</u> Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on General Product Safety	OJ No L 11; 15.01.2002; p. 4-17	---
<u>Community postal services :</u> Directive 97/67/EC of 15 December 1997 of the European Parliament and the Council on common rules for the development of the internal market of Community postal services and the improvement of quality of service	OJ L 15; 21.01.1998; p. 14-25	Directive 2002/39/EC; OJ L 176; 05.07.2002; p. 21-25
<u>Energy labelling of household appliances :</u> Council Directive 92/75/EEC of 22 September 1992 on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances	OJ L 297; 13.10.1992; p. 16-19	---

Waste electrical and electronic equipment (WEEE) :

Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) - Joint declaration of the European Parliament, the Council and the Commission relating to Article 9

OJ L 37; 13.02.2003;
p. 24-39

Directive 2003/108/EC;
OJ L 345; 31.12.2003; p. 106-107

(http://ec.europa.eu/enterprise/mechan_equipment/machinery/mandates/m-396_en.pdf)



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Aerospace, security, defence and equipment
Mechanical and electrical equipment

Brussels, 19th December 2006
M/396 EN

Mandate to CEN and Cenelec for standardisation in the field of machinery

1. BACKGROUND

1.1. The legal basis of the mandate

This mandate relates to Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC¹. This Directive is a revision (recast) of the current Machinery Directive 98/37/EC². It came into force on 29 June 2006. Its provisions must be transposed into the national law of the Member States by the 29th June 2008 and will become applicable on 29 December 2009.

According to Article 5(1) of the revised Directive, machinery subject to the Directive must satisfy the relevant essential health and safety requirements set out in Annex I before being placed on the market. Article 7(2) of the revised Directive states that machinery manufactured in conformity with a harmonised standard, the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with the essential health and safety requirements covered by the standard.

The scope of the revised Directive, set out in Article 1, is extended in so far as certain types of machinery have been removed from the list of exclusions. The borderline between the scope of the Machinery Directive and other Directives, in particular, the Low Voltage Directive, 73/23/EEC³, and the Lifts Directive, 95/16/EC⁴, have been redefined in order provide greater legal certainty.

Compared with the current Machinery Directive, Annex I to Directive 2006/42/EC does not introduce major changes to the essential health and safety requirements applicable to machinery. However, several of these requirements, such as those relating to ergonomic principles and machine emissions, have been made more precise. A limited number of new essential health and safety requirements have been introduced to deal with risks associated with the types of machinery brought into the scope of the Directive.

¹ OJEU L 157, 9.6.2006, p. 24–86.

² OJEC L 207, 23.7.1998, p. 1–46.

³ OJEC L 77, 26.3.1973, p. 29–33.

⁴ OJEC L 213 of 7.9.1995, p. 1 – 31.

Furthermore, certain requirements that are currently applicable only to mobile or lifting machinery have been made applicable to any machinery presenting the risks concerned.

1.2. The aim of the mandate

The aim of the mandate is to invite CEN and Cenelec to check the existing body of harmonised standards supporting the Machinery Directive and to carry out the necessary adaptations to the standards ensure that :

- harmonised standards are available to cover the scope of the revised Directive 2006/42/EC;
- harmonised standards for machinery provide specifications enabling manufacturers to comply with the revised essential health and safety requirements of the revised Directive.

2. DESCRIPTION OF THE MANDATED WORK

The Commission requests CEN and Cenelec to check the existing body of standards for machinery and, where necessary, to draw up new standards or to amend or revise the existing standards in order to ensure that they cover the scope and satisfy the essential health and safety requirements of the revised Machinery Directive 2006/42/EC.

The existing standards concerned by this mandate are the standards, the references of which have been published in the OJEU in support of Directive 98/37/EC, that were developed in response to successive mandates relating to Directive 89/392/EEC as amended and Directive 98/37/EC, in particular, the programming mandate M/BC/CEN/91/16 and the standardisation mandate M/079. This mandate also concerns new and revised standards for machinery to be adopted during the period leading up to the application of Directive 2006/42/EC.

The standardisation tasks covered by this mandate are as follows :

- 2.1. Ensure that harmonised standards are available to cover the categories of machinery introduced into the scope of the revised Directive (in particular, construction site hoists and portable cartridge-operated fixing and other impact machinery) ;
- 2.2. Make the necessary adjustments to standardisation to take account of the redefined borderline between the Machinery Directive and the Low Voltage Directive and the fact that certain types of machinery, currently subject to the LVD, may become subject to the MD ;
- 2.3. Make the necessary adjustments to standardisation to take account of the fact that Directive 2006/42/EC amends the Lifts Directive 95/16/EC with the effect that lifting appliances with a speed no greater than 0.15 m/s are subject to the Machinery Directive ;
- 2.4. Ensure that the harmonised standards intended to support Directive 2006/42/EC fully satisfy the relevant essential health and safety requirements of the revised Directive or, failing that, include an indication as to which of the requirements are not satisfied ;

- 2.5. Ensure that the standards intended to support the revised Directive include an indication of the relationship between the clauses of the standard and the essential health and safety requirements of Annex I to Directive 2006/42/EC⁵ in accordance with the agreement on this subject between the Commission and the European Standardisation Organisations.⁶

3. EXECUTION OF THE MANDATE

- 3.1. CEN and Cenelec are requested to communicate to the Commission, by 30 September 2007, a work plan for the execution of the abovementioned standardisation tasks, indicating the new standards that need to be developed, the standards requiring revision or amendment and the standards for which the introduction of a reference to Directive 2006/42/EC is sufficient.
- 3.2. CEN and Cenelec are requested to communicate to the Commission by 30 June 2008, an interim report on the progress of the tasks set out in this mandate, indicating any eventual difficulties encountered.
- 3.3. CEN and Cenelec are requested to communicate to the Commission, by 30 June 2009,⁷ a list of harmonised standards supporting Directive 2006/42/EC. The list shall include the titles of the standards in all of the official languages of the EU.
- 3.4. CEN and Cenelec are requested to draw up the work plan and execute the abovementioned tasks in close cooperation in order to ensure consistency and avoid overlapping standards, particularly with respect to task 2.2 relating to the borderline between the Machinery Directive and the Low Voltage Directive.
- 3.5. When executing the standardisation tasks covered by this mandate, CEN and Cenelec are requested to take due account of feedback from the end-users of the machinery concerned.
- 3.6. Wherever possible, when the abovementioned tasks involve the development of new standards or the revision of existing standards, the tasks should be executed within the framework of the Vienna and Dresden Agreements with a view to preparing international standards that satisfy the relevant essential health and safety requirements of Directive 2006/42/EC.
- 3.7. CEN and Cenelec are requested to make available to the Commission the texts of the standards developed on the basis of this mandate (including the European standards based on international standards) in English, French and

⁵ If the specifications of a harmonised standard satisfy the essential health and safety requirements of both the current and revised Machinery Directives, it is possible to include in the standard an informative reference to both Directives.

⁶ *Indication of the relationship to essential requirements in harmonised standards (Annex Z) Implementation by the European Standards Organisations - 98/34/EC Committee Doc.2004/35, 31 August 2004.*

⁷ The Commission intends to publish such a list in the OJEU before the revised Directive becomes applicable.

German.

- 3.8 Acceptance by CEN and Cenelec of this mandate starts the “standstill” period referred to in Article 7(1) of Directive 98/34/EC⁸.

⁸ OJEC L 204, 21.7.1998, p. 37.



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
New Approach Industries, Tourism and CSR
Director

■ Ref. Ares(2013)111870 - 29/01/2013

September 2009

EU contribution

The use of voluntary standards in support of EU legislation

1. INTRODUCTION

The present document represents the EU contribution to a Joint EU-US report describing the respective approaches in the US and EU to the use of voluntary standards in support of regulation. It has been elaborated following a request from the EU-US High Level Regulatory Forum (HLRF) in accordance with a commonly agreed outline for the report.

The aim of this report will be:

- * to provide a better mutual understanding of respective policies, the legal frameworks and methods of using voluntary standards in support of regulation in both the EU and the US;
- * to share experiences within the HLRF with respect to the approaches followed as well as the commonalities and differences of both sides' regulatory approaches;
- * to stimulate regulatory cooperation with a view to making more extensive use of voluntary standards in certain areas, preferably international standards in support of regulation following a coordinated approach.

For the purpose of this document, the term "regulation" refers to acts of EU legislation (such as Regulations, Directives, Decisions) adopted by the EU legislator (European Parliament and Council, and Commission in the case of derived legislation). Standards are documents adopted by private sector standardisation bodies and they are not mandatory.

Various kinds of links between regulations and voluntary standards may be found within EU legislation. This report focuses on the principal regulatory policy of the EU that makes use of voluntary standards, known as the "New Approach" method. It has played an essential role in the completion of the EU's Internal Market in a significant number of industrial sectors for the last 25 years. The "New Approach" legislative method is applied to EU legislation which regulates the protection of health, safety, consumers, environment and other public interests with regard to the placing of products on the EU market. The use of standards following this method is illustrated through four examples referring to safety in the area of electrical equipment, safety of machinery, safety of medical devices and electromagnetic compatibility.

Besides the New Approach method as described in this report, numerous other specific cases can be found where voluntary standards are used in support of/or referenced in EU legislation. These cases and the solutions applied reflect specific regulatory needs and should be considered on the merits of each case.

Furthermore, the report describes the use of voluntary standards in the context of public procurement.

2. POLITICAL AND LEGAL CONTEXT OF THE USE OF STANDARDS IN SUPPORT OF EU LEGISLATION

The political and legislative framework for the use of voluntary standards in support of EU legislation was renewed by the European legislator in 2008. In their Decision 768/2008/EC¹ and the Regulation (EC) 765/2008/EC², the European Parliament and the Council adopted a New Legislative Framework for the marketing of products in the EU. The aforementioned Decision 768/2008/EC constitutes a general horizontal framework for the revision of existing and the drafting of future sector legislation harmonizing the conditions for placing products on the market. Among other things, it sets out the principles and reference provisions governing the use of voluntary standards in the regulatory context.

According to one of the key principles of the Decision, EU legislation should avoid excessive technical detail and, when applying this concept, restrict itself to defining the **"essential requirements"** which determine the level of protection of public interest at stake. For Internal Market legislation, public interest includes the protection of consumers, health, safety, environment, energy efficiency and any other relevant aspects. EU legislation which follows this concept should refer to **"harmonised standards"** adopted by the European Standards Organisations (ESOs) CEN³, CENELEC⁴ and ETSI⁵. It is then the role of the harmonised standards to express the legal requirements in technical terms.

The leading principle of harmonised standards is that they remain **voluntary**. Manufacturers are free to choose any appropriate solutions to ensure that their products comply with the legal "essential requirements". They may opt for the solutions offered by harmonised standards but they may equally opt for any other compliant solution. The advantage of using harmonised standards is that manufacturers then benefit from the so-called **"presumption of conformity"** with the legal requirements.

The origins of this concept can be found in a Resolution of the Council on "A New Approach to technical harmonisation and standards" adopted in May 1985⁶. The New Approach was conceived by the Commission in response to previous failures in the legislative process of several technical harmonisation projects which had been drawn up in a rather over prescriptive manner. As already mentioned it has since become a key part of the EU's strategy for the completion of the Internal Market.

¹ OJ L 218, 13.08.2008, p. 82

² OJ L 218, 13.08.2008; p. 30

³ Comité européen de normalisation, avenue Marnix 17; B-1000 Brussels (www.cen.eu)

⁴ Comité européen de normalisation électrotechnique, avenue Marnix 17; B-1000 Brussels (www.cenelec.eu)

⁵ European Telecommunications Standards Institute, 650, route des Lucioles, F-06921 Sophia Antipolis Cédex (www.etsi.eu)

⁶ OJ C 136, 04.06.1985

The "New Approach" concept has been reviewed and further developed over time to include also conformity assessment⁷. The Decision 768/2008/EC together with Regulation (EC) No. 765/2008⁸ relating to accreditation and market surveillance now constitute the EU's new legislative framework for the placing of products on the EU market.

Legislation has been introduced following this method in more than 20 different sectors. This has played a central role in the European Commission's endeavour to improve the free movement of goods and to ensure a high level of protection. It is estimated that the major part of industrial products marketed in the EU is regulated under "New Approach" legislation"

In addition to the regulatory method for the use of voluntary standards provided by the New Approach concept, the EU has developed and implemented a framework to promote the elaboration of the necessary European Standards. This framework is embodied in Directive 98/34/EC⁹ which lays down an information procedure in the area of technical regulations and standards.

With the aim of supporting the creation of a single European market, Directive 98/34/EC

- * provides a **procedure for exchanging information about national standards and programmes** between the Member States, the Commission, the national and standards bodies and the ESOs;
- * **recognises CEN, CENELEC and ETSI** as the "European Standards Organisations" and identifies the national standards bodies which are - due to the obligations for Member States resulting from the Directive - subject to the relevant requirements of the Directive;
- * enables the Commission to address a "**standardisation request**" to the European Standards Organisations ("standardisation mandates") for defined subjects;
- * obliges the Member States to abstain from introducing national standards in areas where a standardisation request was entrusted to the European Standards Organisations ("**standstill**").

Directive 98/34 requires the Commission to consult the Member States through an Advisory Committee before addressing any standardisation requests to the European Standards Organisations. It lays down the foundation for the current European standardisation system which is, in essence, based on key responsibilities of the European and national standardisation bodies.

⁷ Council Decision 93/465/EC (OJ L 220, 30.08.1993); Council Resolution of 28.10.1999 on the role of standardisation in Europe (OJ C 141, 19.05.2000)

⁸ Decision 768/2008/EC of the European Parliament of 9 July 2008; Regulation (EC) 764/2008 of the European Parliament and of the Council of 9 July 2008, OJ L 218, 13.08.2008

⁹ OJ L 204, 21.07.1998; this Directive replaced Directive 83/189/EC (OJ L 109, 26.04.1983)

If the Commission addresses standardisation requests to the ESOs, the latter **are not legally obliged to undertake the standardisation work requested**. They make their decision after consultation of stakeholders organised at national level.

The availability of a **standardisation infrastructure**, in accordance with Directive 98/34/EC, is one of the elements of the "Community acquis", which is to be implemented before new Member States may accede the European Union.

In view of the significant role European standardisation plays in supporting the Single Market and other legislation, sustainable development and a large number of other European policies the Commission and the European Standards Organisations, CEN, CENELEC and ETSI, concluded a **Memorandum of Understanding to govern their relationship**¹⁰. In this MoU the parties recognise European standardisation as an independent, consensus orientated, and voluntary activity. The Commission agrees to make use of European standards in support of European regulation and policies where appropriate and it confirms its intention to provide financial support for activities related to European standardisation.

The ESOs commit themselves to maintaining an infrastructure which meets stakeholders' and societal needs and to ensuring that European standardisation is carried out in accordance with the principles of **consensus, including the interests and participation of all voluntary relevant stakeholders, openness, transparency, independence, coherence, effectiveness and accountability**. The ESOs affirm their commitment to the terms of the WTO TBT Code of Good Practice and to the deference to international standards.

This cooperation agreement is further complemented by Framework Partnership Agreements which allow the Commission to provide financial support to European standardisation. in accordance with Decision 1673/2006/EC of the European Parliament and the Council¹¹.

The "standardisation request" instrument anchored in Directive 98/34/EC in conjunction with the aforementioned cooperation agreements have been pivotal in the implementation of the successful "New Approach" method as well as a large number of other European policies. It is important to note that the overwhelming majority of European standards adopted by CEN, CENELEC and ETSI are elaborated on the stakeholders' initiative. Around 20% of the total output of CEN and CENELEC¹² results from a standardisation request from the Commission. This corresponds to a total number of approximately 400 standardisation requests issued to the ESOs since the setting up of the system¹³. Although the proportion of European standards

¹⁰ General guidelines for the cooperation between CEN, CENELEC, ETSI and the European Commission and the EFTA

¹¹ OJ L 315, 15.11.2006, p. 9

¹² At the end of 2008, out of CEN's 13330 standards documents published, 2071 are considered as harmonised standards. For CENELEC, out of 5525 documents, 1458 are harmonised standards

¹³ Standardisation requests issued to the ESOs are published under http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index_en.htm
Note: this note is applicable to all links which refer to the EUROPA website. The European Commission is currently redesigning the EUROPA website. The reader will therefore be presented with a link to the new website valid as from 01.11.2009. The current "Standardisation policy" website is available until 31.10.2009 at http://ec.europa.eu/enterprise/standards_policy/index_en.htm.

adopted following a standardisation request from the Commission is relatively low, compared to the total standard production of the ESOs, their impact in terms of quality of life and product safety is enormous. Standards adopted in relation to a request from the European Commission to implement a Community policy cover key areas such as health and safety (e.g.: toys, child-care articles, household appliances, machinery, fire safety) and more and more environmental protection and energy efficiency. Moreover the drive to develop European standards on the basis of standardisation requests from the Commission has been a key element in the process following which the centre of gravity has shifted irreversibly from divergent national standards to standards harmonised at European and international level, whilst maintaining in the case of CEN and CENELEC the continuous involvement, technical input and governance of European standardisation through the delegations of the national standards bodies. The standardisation model of ETSI is different as it is based in essence on direct involvement of individual stakeholders in the approval process but voting through national delegations is possible in the case of standards aimed at supporting European legislation.

The assurance given by the European Standards Organisations that they will respect the principles of standardisation, in particular by involving all stakeholders concerned and taking into account public interest, is indispensable if the European regulator is to be able to rely on the use of voluntary standards in a regulatory context.

The implementations of Directive 98/34/EC and of the aforementioned cooperation guidelines constitute the key pillar for European standardisation policy. This policy is shared with the EFTA countries by means of the **European Economic Area (EEA) agreement**.

3. THE CONCEPT OF EUROPEAN "HARMONISED" STANDARDS SUPPORTING EUROPEAN REGULATORY REQUIREMENTS

Standards which become relevant for use in support of a given regulation are called **"harmonised standards"**. In Decision 768/2008/EC those are defined as meaning European standards adopted by one of the European Standards Organisations listed in Directive 98/34/EC and which are adopted in accordance with a standardisation request from the Commission to the ESOs¹⁴. At present CEN, CENELEC and ETSI are recognized through Directive 98/34/EC as the European standardisation bodies. The modification of the listing requires a decision by the Council and the European Parliament on the basis of a proposal from the Commission.

Therefore, in principle, only standards adopted by CEN, CENELEC or ETSI are eligible for use in support of EU legislation following the new Approach method.

¹⁴ See Decision 768/2008/EC, Annex I, Article R1, para. 9

- a) **Role of "harmonised standards"**: Where EU legislation follows the method of the "New Approach", relevant European harmonised standards remain voluntary. They do not form part of the legislation itself. The role given by the legislator to the ESOs is limited to providing guidance on how to achieve compliance with legal requirements. In this context it is also important to note the statement in the "Whereas" of Decision 768/2008/EC, following which the essential requirements should be worded precisely enough to create legally binding obligations. They should be formulated in such a way that it is possible to assess whether products conform even in the absence of harmonised standards or if the manufacturer chooses not to apply a harmonised standard¹⁵.

Public authorities and, where applicable, third party conformity assessment bodies may not impose the application of harmonised standards. However if the manufacturer does apply harmonised standards, the competent authorities and conformity assessment bodies **are to presume that the products in question conform to the legal requirements** addressed by those standards ("presumption of conformity"). The use of harmonised standards presents an advantage for manufacturers as it facilitates in a predictable and officially accepted way the compliance setting.

The effect of the presumption of conformity may be challenged by the authorities in charge of enforcement, if the latter can establish that the standard is not fully compatible with the regulation. In such cases, the Member State has to launch a formal procedure which may culminate in a Commission Decision confirming, refusing or restricting the status of the standard concerned as a "harmonised" standard. Cases of Member States or the Commission objecting to a harmonised standard and the presumption of conformity subsequently being modified through a Decision are rare¹⁶.

¹⁵ Different rules govern standard-making under the General product Safety Directive (2001/95). Contrary to "New Approach" Directives, the GPSD does not contain specific safety requirements. This is a consequence of the fact that the Directive does not apply to a specific product but to any non food consumer product that is not dealt with under a specific "New Approach" Directive.

Under the provisions of the GPSD, the European Commission and the Member States set the safety requirements on a case-by-case basis. These safety requirements are also subject to a 3-months scrutiny of the European Parliament. Once formally adopted, the safety requirements become the basis for a standardisation request to the ESOs and do not create any new set of rights and obligations upon third parties.

¹⁶ **Decision 2004/376/EC** (relating to EN 1970:2000 on adjustable beds); OJ L 118, 23.4.2004;
Decision 2004/389/EC (relating to EN 12181 on non-active surgical implants); OJ L 120, 24.4.2004;
Decision 2006/733/EC (relating to EN ISO 14122-4 on permanent means of access to machinery); OJ L 299, 28.10.2006;
Decision 2006/4901/EC (relating to EN 848-3 on woodworking machines); OJ L 291, 21.10.2006

See also Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee on the operation of Directive 98/34/EC from 2002 to 2005 [COM(2007) 125, 21.03.2007], accompanying Commission Staff Working Document SEC(2007) 350

- b) **How can standards qualify to be used in support of legislation?** The standard needs to derive from a **standardisation request** from the Commission to the ESOs, in accordance with Directive 98/34/EC. The standardisation request ensures that the resulting European standards will be elaborated and adopted in compliance with the relevant legal requirements for which they are expected to provide technical expression. As a general rule, the Commission does not influence the technical solutions to be provided in the standards either in the standardisation request or at a later stage. It is up to the community of all interested parties to agree, in the standards setting process, on the most appropriate and technically sound solutions in compliance with the related protection requirements. With this in mind the ESOs have set up quality control mechanisms to make sure that the adopted standards are in line with relevant legal requirements for which they provide technical expression.

Following a standardisation request the ESOs are responsible for ensuring that the standards are developed in an organised fashion in order that relevant horizontal and products standards fit harmoniously together and that the set of standards to support a particular regulation is fully coherent.

Once the ESOs communicate the titles of European standards adopted following a standardisation request to the Commission, the Commission publishes the references of these standards in the edition C of the Official Journal.

As a general rule, the technical content of relevant harmonised standards is not verified by the Commission; the ESOs provide assurance that the standards may be referenced in the Official Journal as they have been elaborated in accordance with the terms of the standardisation request.

European standards become available at national level as national standards issued by the national standards bodies and are in most cases translated into the national languages.

- c) **Stakeholder involvement in standardisation activities:** Where standards are elaborated to support European legislation, it is essential that all relevant stakeholders have access to the standardisation activities and that they become involved. The term "**stakeholders**" may mean manufacturers, users, testing and conformity assessment bodies, public authorities, consumers, SMEs and non-governmental organisations representing societal interests (e.g. environment, workers protection) depending on the subject of the standardisation work.

The Commission does in general not have any input in the technical content of specific harmonised standards. As expressed in the cooperation guidelines between the Commission and the ESOs, the latter are committed to ensuring that standardisation activities are carried out in association with all the parties concerned and that the results are based on consensus. The national standards bodies have an important role to play in organising the involvement of stakeholders and in running the process of public enquiries for draft standards at national level.

The Council of Ministers has highlighted the need for adequate representation of the relevant stakeholders in standardisation activities several times¹⁷. Notwithstanding the importance of the involvement of interested parties at national level, the Commission particularly supports the participation of European NGOs representing the interests of consumers, workers, SMEs and environmental protection in activities of European and international standardisation¹⁸.

A recent study on the access to standardisation commissioned by the Commission confirmed the need for further improvement¹⁹ in this regard.

- d) **How are the interested parties informed about relevant standardisation activities and harmonised standards?** Where a regulation makes use of voluntary standards this is clearly stipulated in this regulation. Standardisation requests which are addressed to the ESOs by the Commission usually prior to the first date of application of the regulation are published on the Commission's website²⁰. In addition the ESOs provide continuously updated information on activities relating to harmonised standards through a New Approach portal²¹. The National Standards Bodies provide information on ongoing public enquiries related to European standards. The references of harmonised standards together with information about the related EU regulation and corresponding international standards is published by the Commission in the Official Journal and on its website²².

¹⁷ Council Conclusions of 1 March 2002 on standardisation, OJ C66, 15.3.2002. Council Conclusions on standardisation and innovation, 25.9.2008, http://ec.europa.eu/enterprise/policies/european-standards/files/standards_policy/standardisation_innovation/doc/councilconclusions_20080925_en.pdf

¹⁸ Following European organisations are involved : Consumers = ANEC (www.anec.eu); Workers = ETUI (<http://hesa.etui-rehs.org/>); PME = NORMAPME (www.normapme.com); Environment = ECOS (www.ecostandard.org)

¹⁹ http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/policy-review/access-to-standardisation/index_en.htm

²⁰ http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/database-mandates/index_en.htm

²¹ www.newapproach.eu/

²² http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

- e) **Mechanisms to ensure the maintenance, revision and updating of harmonised standards**: The regular updating of harmonised standards and their adaptation to technical progress falls within the remit of the ESOs. The ESOs are committed to ensuring that the references of new and revised harmonised standards are updated and communicated to the Commission for publication.

In given cases, for example, where a shortcoming of a standard is established in the context of market surveillance, the Commission addresses a specific standardisation request to the ESOs, asking for the standard in question to be corrected or improved.

- f) **How are international standards used?**: Following the New Approach method confirmed by Decision 768/2008/EC, the EU regulator makes use of European harmonised standards adopted by one of the three ESOs. At the same time the EU deals with its obligations from the WTO TBT to rely on existing or imminent international standards "as a basis" for its technical regulation where this is possible.

The Commission²³, supported by the Council²⁴, considers in the regulatory context that "international standards" are those adopted by the international standardisation bodies ISO and IEC on the basis of national representations that are responsible for establishing consensus between all national positions and interested parties. This ensures, in accordance with the need to rely on accountable bodies, that the constituency of international standardisation bodies is clearly defined and that a coherent set of standards can be used where conflicting standards are withdrawn at national level.

Through the cooperation agreements with the Commission, the ESOs are obligated to take up as far as possible international standards. This is put into practice through the Vienna Agreement with ISO in CEN's case and the Dresden Agreement with IEC in CENELEC's case.

The Vienna Agreement recognises the primacy of ISO standards and sets out modes of coordination and cooperation between both partners. **Fully identical ISO and CEN standards** may be adopted as EN ISO standards through parallel procedures lead either by ISO or by CEN. Where within international standardisation fully harmonised technical solutions are not possible, for example due to regulatory constraints, the standardisers are encouraged to cover the largest common denominator.

Similarly the Dresden Agreement between CENELEC and IEC sets up the principles of cooperation and allows in particular for the **adoption of identical standards** by parallel procedures. The identical ISO or IEC standards can be traced through the references of the European standards.

²³ SEC (2001) 1296, 26.07.2001

²⁴ Council conclusion on standardisation of 1 March 2002, OJ C 66, 15.03.2002

Over a period of several years it has been a continuously growing trend that CEN adopts ISO standards. By the end of 2008, out of the 13.330 European standardisation documents adopted by CEN, 3639 (27%) had been adopted as EN ISO standards as a result of the Vienna Agreement. In addition, about 9900 ISO standards have been adopted directly by the EU's national standards bodies independently from CEN.

As for CENELEC, about 75% of its deliverables are identical to or based on IEC standards. In principle, this proportion also applies to harmonised standards.

According to the terms of the Vienna and Dresden Agreements, if the Commission addresses a standardisation request to the ESOs for European standards in support of European legislation, standardisation activities may be organised in such a way that standards are elaborated under the leadership of ISO or IEC. Coordination with the international standards bodies is regularly requested in the Commission's standardisation requests.

It is not essential that standards are first developed at European level. However, should ISO or IEC take the lead, the ESOs must ensure that the resulting International/European standards comply fully with the European regulatory requirements and are suitable for use as "harmonised standards".

The Commission is aware of only a few cases where, due to regulatory requirements aiming at protecting public interests, it was not possible to achieve completely harmonised identical standards.

It is worthwhile noting that in a number of cases (e.g. medical devices, machinery, construction products, ...), where, in the absence of international standards, the first generation of standards was elaborated at European level and the revision of those standards was then transferred to the international level in accordance with the Vienna and Dresden Agreements, resulting in the common approval of identical European/international standards.

The Vienna and Dresden Agreements have proven to be very successful in the sense that the number of identical international and European standards has been continuously extended and that the needs of the stakeholders have been served in the best way.

The implementation of international standards through European standards ensures a uniform application of such standards for the entire European Economic Area.

4. APPLICATION OF THE NEW APPROACH METHOD

Since 1985 the New Approach method has been the key concept in EU legislation for the Single Market in the sectors of mechanical and electrical engineering, construction products, medical technology and several others. It has essentially contributed to the free movement of goods whilst ensuring a high level of protection of consumers, workers, health, safety, environment and other public interests. All the features of the New Approach (use of standards, conformity assessment, CE marking) have been applied for more than 20 acts of EU legislation (see Annex 1)

Furthermore, numerous other EU regulations foresee the use of voluntary European standards with the aim of providing further technical expression of the legal requirements. These other areas include general product safety, rational use of energy for buildings and products, interoperability of railways systems, airborne noise, airworthiness, marine equipment, electronic communication services (see Annex 1²⁵).

In cases where the legislator relies on voluntary standards, the Commission, as a general practice, addresses standardisation requests to the ESOs in order to cover the regulatory needs.

The European Standards Organisations have successfully managed to deal with the Commission's requests. Generally the stakeholders are committed to contributing to the drafting of standards and to making their expertise available on a voluntary and non-remunerated basis. By 2009 the ESOs have adopted about 5000 European standards which qualify as "harmonised standards".

More detailed information is provided for four cases of applications of the New Approach method in sector legislation :

Example 1 : Low Voltage Directive : The "Low Voltage Directive" was first adopted in 1973 then it was amended in 1993 and finally codified in 2006 (Directive 2006/95/EC²⁶). From its first adoption in 1973, this Directive was the precursor of the "New Approach" concept. At a very early stage of the Internal Market it relied to a large extent on voluntary standards adopted by CENELEC.

²⁵ See also Commission communication COM(2004) 674 on the role of standardisation in the framework of European policies and legislation, Commission Staff working paper on the challenges for European standardisation (http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/role-european-standardisation_en.htm) containing further references; those "other EU regulations" referencing to voluntary standards may present some divergences to the "New Approach" method.

²⁶ Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (codified version); OJ L 374; 27.12.1996; Article 14 repealed the former Directive 73/23/EEC (OJ L 77; 26.03.1973); the text of Directive 73/23/EEC, as amended by Directive 93/68/EEC, was not modified at the occasion of the codification

The Directive covers health and safety related risks in view of the placing of electrical equipment on the market ensuring a high level of protection and a Single Market in the European Union. The scope includes electrical equipment designed for use within determined voltage ratings²⁷. The Low Voltage Directive regulates for example electrical appliances, lighting equipment, electric motors, switch and control gear, electrical installation equipment.

The essential safety requirements are drafted in rather generic terms.

The Directive guarantees for the aspects covered the free circulation of electrical equipment on the European market whilst ensuring a high level of protection.

As the original version of the Low Voltage Directive was already adopted in 1973, some particular provisions with regard to the recognition of "harmonised standards" apply.

In support of the Low Voltage Directive 602 European harmonised standards addressing safety issues have been adopted by CENELEC²⁸. The large majority of these standards (about 380) were elaborated under the IEC lead in accordance with the Dresden Agreement; these standards are entirely identical with the corresponding IEC standards. 132 more harmonised standards are based on IEC standards but contain modifications which take into account particular European needs.

In very few cases, the Commission has issued specific standardisation requests to CENELEC asking for a revision of existing standards in order to ensure a high level of protection. These cases refer to :

- * protection against electromagnetic fields;
- * surface temperatures of appliances;
- * safety of household appliances with respect to the protection of children, older people and people with disabilities;
- * safety of tanning devices for cosmetic purposes.
- * safety of personal music players

The relevant standards have since been improved or are subject of a review.

Example 2 : Machinery Directive : Directive 2006/42/EC on Machinery²⁹ regulates the health and safety related risks related to the design and construction of machinery. The scope includes both machinery for professional and consumer use.

The essential health and safety requirements of the Directive take a risk-orientated approach and compel the manufacturer to perform a risk assessment concerning the design and construction of his machines.

Harmonised standards from CEN/CENELEC play an important role in addressing technical risks which may be associated with machines.

²⁷ Between 50 and 100 V for alternating current; between 75 and 1500 V for direct current

²⁸ OJ C 126 of 05.06.2009; p. 22-100

²⁹ OJ L 157; 09.06.2006; p. 24

In accordance with the Commission's request, CEN and CENELEC have implemented a standardisation programme which follows a three tiered structure of standards in a systematic way:

- * type A standards relating to basic concepts and principles of design applicable to nearly all machines;
- * type B standards dealing with safety aspects (e.g. noise, temperature) and safeguard aspects (e.g. guards, control systems) for a large range of machines;
- * type C standards dealing with particular risks of given product groups of machinery.

By this year a coherent set of about 579 harmonised standards covering the application of the Machinery directive has been adopted³⁰. So far about 114 standards are identical with ISO/IEC standards and many other harmonised standards are already based on international standards. Whilst the first generation in the area of CEN standards had to be elaborated at European level, the proportion of international standards is growing continuously since the revision of the standards has been transferred to ISO (e.g. the former type A standard EN292 relating to design principles for machinery has become EN ISO 12100).

Following the adoption of the revised and consolidated Machinery Directive 2006/42/EC, the Commission has issued a general standardisation request for the adaptation of harmonised standards to support the revised directive (Annex 2).

The reliance on standards in this area works satisfactorily. Some problems have been encountered where harmonised standards had shortcomings in terms of the safety requirements for :

- * permanent means of access;
- * mobiles cranes;
- * lifting platforms;
- * chain saws and woodworking machines

Particular standardisation requests on these issues were addressed to CEN/CENELEC and the list of harmonised standards was modified accordingly³¹.

Example 3 : medical devices : The regulatory framework for medical devices consists of **3 main directives**:

- * Directive 90/385/EEC regarding Active Implantable Medical Devices³²
- * Directive 93/42/EEC regarding Medical Devices³³
- * Directive 98/79/EC regarding *in vitro* Diagnostic Medical Devices³⁴

and **several amending and implementing measures** (e.g. regarding non-viable animal tissues and cells, device/blood derivatives combination products, reclassifications).

³⁰ List of harmonised standards; OJ C 74; 28.03.2009; p. 4

³¹ http://ec.europa.eu/enterprise/sectors/mechanical/documents/standardization/machinery/index_en.htm

³² OJ L 189; 20.07.1990; p. 17-36

³³ OJ L 169; 12.07.1993; p. 1-43

³⁴ OJ L 331; 07.12.1998; p. 1-37

The legal essential health and safety requirements aiming to protect patients, users and workers are technology-neutral so manufacturers can choose their preferred solution to meet the legal requirements. However, compliance with the specifications of “harmonised standards” gives a presumption of conformity to the legal requirements.

Standardisation work is done mainly by CEN/ISO, but also by CENELEC/IEC. The Commission published **the references of about 300 harmonised standards** for all three directives :

of which more than 70% are entirely identical with or based on ISO/IEC standards

Despite the fact that the interaction between regulation and standards generally works well, it has been noted recently that some standards foreseen for publication in the OJ did not fully correspond with the legal requirements (e.g. labelling, aspects not covered by the directives).

The role of standards in the assessment of medical devices has been **recognised by the Global Harmonization Task Force on medical devices (GHTF)** in its recently adopted Doc. GHTF/SG1/044:2008 (see Annex 3).

It is stated in this document that “*international consensus standards are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices*”.

The GHTF document further recommends that regulatory authorities use “recognised standards” which are deemed to offer the presumption of conformity to essential principles of safety and performance.

Aptness of standards for the Medical Devices sector : the medical devices industry operates on a **truly global market**. Technical solutions are mostly valid worldwide. Globally accepted specifications are more easily found in standards than in regulations.

Regulators of the main markets have agreed to **converge their regulatory models** (GHTF and Asian Harmonization Working Party).

Example 4 : electromagnetic compatibility : Directive 2004/108/EC on electromagnetic compatibility³⁵ represents a revision of the original EMC directive adopted in 1989³⁶. It regulates the ability of electrical equipment to function satisfactorily in its electromagnetic environment.

The essential requirements related to electromagnetic compatibility (disturbance and immunity to disturbance) are very generic. European standardisation has played a very important role in providing a common playing field for the application of this Directive.

³⁵ OJ L 390; 31.12.2004; p. 24-37

³⁶ Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 139; 23.05.1989; p. 19-26)

144 harmonised standards adopted by CEN, CENELEC and ETSI have been listed in support of this Directive,³⁷ of which 70 are identical with ISO/IEC standards and a significant number of the remaining standards (29) are based on international standards.

The use of voluntary standards in support of EMC legislation functions in principle in a satisfactory manner; One of the problems encountered consists of finding the right economic balance between opposing interests (disturbance, immunity) in particular where different equipment is expected to be used in the same environment.

5. USE OF STANDARDS IN THE FRAMEWORK OF PUBLIC PROCUREMENT

The procedures for the award of public work contracts, public supply contracts and public service contracts are harmonised in the EU under Directive 2004/18/EC of the European Parliament and the Council³⁸. Article 23 in conjunction with Annex VI of this Directive stipulates the requirements for setting out the technical specifications governing the contract documentation.

The technical specifications should be formulated in accordance with different options, by using either :

- * identified technical specifications, such as standards or
- * in terms of performance or functional requirements or
- * as a combinations of the above-mentioned options.

When using given technical specifications, references should be made,

" in order of preference to national standards transposing European standards, European technical approvals, common technical specifications, international standards, other technical reference systems established by the European standardisation bodies or – when these do not exist – to national standards, national technical approvals or national technical specifications relating to the design, calculation and execution of the works and use of the products. Each reference shall be accompanied by the words "or equivalent".

A tender cannot be rejected on the grounds that the products or services do not comply with the specifications including standards indicated, once the tenderer has proven that his solutions are equivalent.

Directive 2004/18/EC defines the term "standard" as a technical specification approved by a recognised standardising body and which is either, in accordance with the definitions of Directive 98/34/EC, an international, European or national standard.

³⁷ OJ C 126; 03.06.2009; p. 1

³⁸ Directive 2004/18/EC, OJ L 134, 30.04.2004; p. 114

The provisions of Directive 2004/18/EC are fully coherent with Directive 98/34/EC and the concept of the New Approach.

The Directive provides for flexibility with regard to compliance with standards.

Decision 87/95/EEC³⁹ contains some specific public procurement provisions in the area of ICT. These allow specifications or standards other than those defined in Directive 98/34/EC⁴⁰ to be applied under certain conditions.

In a number of policy areas, such as "access for all" or in the sector of Defence Procurement, standards have been considered a means of achieving defined policy objectives. Accordingly, standardisation requests for the elaboration of European standards were addressed to the ESOs.

6. CONCLUSIONS FROM THE EUROPEAN POINT OF VIEW

The European experience of making use of voluntary standards to support EU legislation is very positive.

The New Approach method and the use of harmonised European standards has made a proven **contribution to the abolition of barriers to trade, the avoidance of new barriers and the improvement of to the functioning of the European Single Market**. The benefits of establishing compliance to legal requirements with the help of harmonised (European and international) standards are available to all suppliers of goods regardless of whether they are established inside or outside the EEA.

The use of standards in support of EU legislation following **the New Approach has become a substantial element of the European Better Regulation policy**⁴¹. In accordance with the objective of simplification, it provides a means of avoiding over-prescriptive regulatory specifications, limiting the legal requirements to the essential and providing further technical expression through voluntary means. At the same time, it relies on the knowledge, experience and skills of all the relevant stakeholders who become involved in the regulatory approach.

From an Internal Market point of view, the use of harmonised standards and the reliance on the stakeholders for their elaboration has been beneficial to the integration of the economy. Due to the transfer of knowledge and know-how aggregated in standardisation, the coming up of new economic actors, in particular from the new Member States, is being supported.

³⁹ OJ L 36, 07.02.1987; p. 31

⁴⁰ The revision of this Decision has been announced; see the Commission's White paper : Modernising ICT standardisation in the EU – The Way forward; COM(2009) 324; 03.07.2009

⁴¹ Communication of the Commission implementing the Community Lisbon Programme : a strategy for the simplification of regulatory environment (COM(2005) 535 of 25.10.2005)

The **involvement of all relevant stakeholders** in the process of European standardisation is vital. This remains a challenge and must be continuously improved.. This is even more relevant for those stakeholders such as consumers, environmental NGOs, which may not be directly linked to the commercial benefits related to the marketing of goods and services.

There are no indications suggesting that the reliance on voluntary standards might affect the effectiveness of regulations in achieving a high level of protection. On the contrary, the use of standards may enhance the level of protection of health and safety as they specify the state of the art and can easily be adapted to its evolution. The New Approach method encompasses sufficient **mechanisms to manage possible shortcomings within harmonised standards in terms of protection and to ensure accountability of standardisation bodies**. Where shortcomings have been identified, the necessary remedies could in principle be found. Nevertheless the **inclusion of public authorities as stakeholders in the standardisation process needs to be further strengthened**.

For the addressees of regulations, in particular the market actors, the New Approach has proven to be flexible and favourable, accommodating the needs of innovative technologies. The stakeholders, in particular businesses, are generally very supportive of this approach as it relies on their contribution, provides a level playing field for establishing regulatory compliance, and at the same time permits flexibility.

The relevant harmonised standards applicable including their possible identity with international standards can be easily identified

The New Approach method is fully in line with the international Regulatory Model adopted by UN/ECE. It is open for further extending international harmonisation. Thanks to the coordination agreement between the European and international standardisation bodies, the proportion of international standards uniformly applied through European standards has continuously increased. The European Standards Organisations and also the international standards bodies, have been very committed to this method and very cooperative in its implementation.

The New Approach concept has proven to be a very successful regulatory method which is increasingly being applied in new areas of legislation, such as eco design and environmental protection.

The existence of a legal framework for European standardisation provided by Directive 98/34/EC including the instrument of standardisation requests, the cooperation of the European and national standardisation organisations and their commitment to be accountable to the public constitute a prerequisite for the success of the New Approach.

Annex 1	EU legislation making use of voluntary standards
Annex 2	Mandate to CEN and CENELEC for standardisation in the field of machinery
Annex 3	Global Harmonisation Task Force : role of standards in the assessment of medical devices

Comments

Brussels, 26 October 2012

Orgalime input on regulatory issues for possible future EU-US trade agreement

1. Introduction

The European engineering industries are export oriented and in total run a healthy trade surplus with other world economies. Despite the current difficult economic setting – the transatlantic trade and investment relationship continues to account for the largest economic relationship in the world, and the EU and the US economies account together for about half of the entire world GDP and for nearly a third of world trade flows.

Orgalime believes that liberalising transatlantic trade and investment should be the first priority of the future EU-US trade and economic relationship. The focus of the economic cooperation should be placed on the trade in goods and services, as well as on regulatory issues. In Orgalime's view, the EU-US relationship has an unexploited potential and we strongly supports increased transatlantic cooperation. We therefore welcome the opportunity to provide the Commission with suggestions on how to make regulatory regimes more compatible across the Atlantic.

For EU companies in our industry, one key barrier on the US market is the malfunctioning of the US certification market. We therefore urge the European Commission to find a solution to this core challenge which has preoccupied our companies since many years. We go further into detail on this hereafter as well as highlighting other issues.

2. Barriers of regulatory nature that are of a concern for companies from the engineering industry

In US, there is a legal obligation for 3rd party product certification for finished products ready for end use, such as a complete machine, in a professional environment. As is often the case, safety relevant components like control devices, circuit boards, cables, etc. are supplied by separate component manufacturers. Consequently, manufacturers of such components need a certification for their products that is recognised by the product testing and certification organisation/company of the complete product. Otherwise, the components would not be marketable in the USA.

OSHA (Occupational Safety and Health Administration) is the governmental body that accredits all the National Recognized Test Laboratories (NRTL). All the NRTLs have the same legal standing and are viewed as technically equivalent, if their scopes of accreditation include the same US national standard. Furthermore, according to the principle of separable certification domains, all organisations/companies that have a NRTL status are allowed to determine that specific products meet consensus-based standards of safety. Therefore, each of their certificates is considered to give the assurance, required by OSHA, that the products are safe for use in a US workplace. This way, there is interconnection among the NRTLs' certificates.

Clients have "in principle" freedom of choice between different NRTLs, even when it comes to certifying components of the same product. What is more, the NRTL chosen by the component supplier shall not restrict the manufacturer of the end-product in terms of choosing a NRTL.

Orgalime, the European Engineering Industries Association, speaks for 33 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.6 million people in the EU and in 2009 accounted for some €1,427 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

www.orgalime.org

However, NRTLs are free to set an operating policy that includes barriers to data acceptance. If an NRTL refuses to accept another's data, it is rejecting OSHA's accreditation or deeming it insufficient. Consequently, the principle of separable certification is questioned by this certification body, which may not accept the certificates produced by other NRTLs. This behaviour of course restricts the choice of customers, as they cannot submit for certification to this specific NRTL a machine that includes components approved by other NRTLs.

➤ Current problem:

Most NRTLs accept certificates issued by other NRTLs with one notable exception: the market leader, UL, which due to historical reasons occupies more than 50% of the market (their market share is estimated at over 70%). UL will issue a certificate for a complete product, in which electrical components are embedded only if UL itself has certified the electrical components beforehand.

Despite their allegations, we consider that UL has no arguments – neither legal nor quality related – for this behaviour. Six of its competitors also hold the additional status of US National Certification Body (US NCB) within the International Electro-technical Commission's (IEC) Certification Body (CB) Scheme. With this scheme, members agree to peer-review audits and mutual recognition of CB Certificates. In this case, UL is obliged to accept test results from all participating NCB's, but the price which manufacturers have to pay for permission to use the UL logo based on testing results by another CB-body is higher than the entire testing procedure by UL itself including the contract for the use of the logo.

Overall, UL removes any incentive to use other NRTLs either by not accepting competitors' certificates or by rendering their use too expensive. Component suppliers are consequently pushed by manufacturing companies to make use of the UL services. Many engineering companies feel that the behaviour of UL constitutes an abuse of a dominant position. Denying recognition of component certificates delivered by other NRTL's causes a quasi monopoly situation. In practical terms, all products need to be reevaluated by UL or a UL-certified supply must be sourced and incorporated. The result is that all products within the electrical component market must be certified by UL and UL's share of the component market is increasing.

3. Impact of the US product certification system on the business activity of EU companies.

The system restricts the choice of manufacturers, proves to be expensive and causes delays in the development process of a machine.

➤ Standards / price differences:

Most NRTLs are non for profit organizations and there is a wide acknowledgement of the high and undoubted competence of UL, there needs to be an investigation as to why, for the same certification projects, the prices of UL are much higher than the prices of CSA (estimates of 3 times higher prices have been observed).

Examples of price differences:

- difference for annual fee between UL vs NTRL x : factor of 2 to 2,5
- difference for audit cost between UL and NTRL x : factor of 3
- audits conducted by other certification bodies, but ordered by UL are paid twice (original certification body + UL)
- administrative updates: cost: factor of 2
- the costs charged for upgrading 2nd & 3rd ed (60601 UL / IEC 60601 2nd & 3rd / IEC 60950 / Demko): update should be done for 20 similar products

➤ Surveillance visits:

For a product approved by a NRTLs, a system of 4 quality surveillance visits a year is imposed on a company. When a company has products approved by different NRTLs, it undergoes 4 visits from each of them, which increases the budget and length of the procedure.

We recommend establishing a quality inspection programme performed by only one NRTL and accepted by all other NRTLs. This is similar to the application of quality systems for equipment manufacturers under the ATEX directive (ISO/IEC 80079-34)

4. A way forward – ensuring a greater compatibility/convergence of the EU and US regulations

Orgalime would like to call upon the EU institutions to encourage US authorities to examine and correct their certification market. Although OSHA set up a certification system in the form of a services market subject to competition, the current rules have a fundamental shortcoming, the lack of obligatory recognition among the NRTLs of component certificates. This allows UL to abuse their dominant position.

Competent US authorities (like the Antitrust Division of the Department of Justice) need to examine this. US component producers suffer from UL's behaviour as well. Suggestions: All NRTLs should, if no obvious fault, be obliged to accept test reports and certificates issued by other NRTLs accredited by OSHA for the scope of the component without retesting, as in Europe.

OSHA's rules for accreditation of NRTLs must clarify that an NRTL in charge of testing a final product cannot be held liable for the failure of the final product caused by the failure of a component certified by another NRTL but otherwise well assembled.

➤ Standards

NRTLs should not set their own standards or interpretation of standards for testing of components or final products but should use national ANSI standards where no international standards of recognized international standards organizations (according to WTO definition of international standards organizations) are available. Considering that most NRTLs are not for profit organizations and that there is wide acknowledgement of the high and undoubted competence of UL, there must be an investigation as to why, for the same certification projects, the prices of UL are much higher than the prices of CSA (estimates of 3 times higher prices than CSA have been observed). UL should not be allowed to create standards that become quasi-obligatory technical requirements for the private sector at a later stage.

The American National Standards Institute (ANSI) and UL take IEC standards, add national deviations and publish them as ANSI/UL standards. Besides, UL uses UL standards for certification which are different from IEC and/or other national standards (as ANSI/ISA, FM, IPC etc.). The US should establish a system similar to EU directives with listed harmonized ANSI standards as a common basis for the conformity assessment by a NRTL. This would lead to transparency and expedite the comparability and interchange ability of conformity assessments between NRTLs. Testing performed by one NRTL would be accepted by other NRTLs when appropriately combined with products tested and certified by a second NRTL.

UL is specialized on electrical equipment and hazards only, and does not look at other possible hazards or other non-electrical products. The UL standards range does not cover hazards from non-electrical causes or physically defined phenomenon like mechanical movements, non-electrical thermal hazards, hazards caused by movement or material properties. Therefore the evaluation of safety relevance reported in UL certificates is incomplete.

➤ Quality Assessment

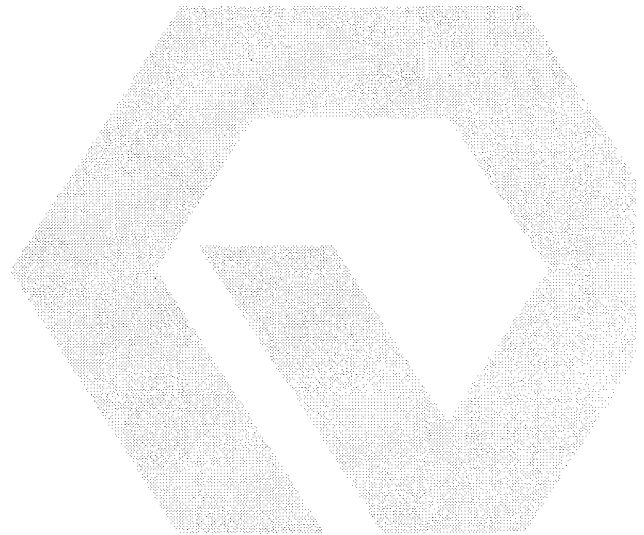
Reports accepted for market entry in USA Certificates of Conformity (CoC) and test reports accepted for products delivered to the USA and Canada USA, like the EU, Japan, recognise IEC standards, as the US National Committee has voted in favour of the standards and when those standards have become US practices.

The US should enter into the worldwide system for conformity, testing and certification of electro-technical equipment and components (the full certification scheme of IECEE). The US needs to expand the possibilities of global technical barrier free trade (GTBFT), with the worldwide system of conformity, testing and certification

5. Conclusions

Although the EU and the US have a long standing tradition of cooperation, we feel that in the electro-technical area the US policy has so far been very inward-looking and non-cooperative. We hope the upcoming negotiations will foster a political change.

Orgalime suggests that the European Commission encourages the US authorities to study the facts and correct the malfunctioning of their certification market. Although OSHA's original intention was to set up a certification system in the form of a services market subject to competition, the current rules governing the market have one fundamental shortcoming, namely the lack of obligatory recognition among the NRTLs of component certificates. This element, as exploited currently by the market leader, allows him to abuse his dominant position in the market. The practice of denying recognition of component certificates delivered by other NRTL's causes de facto a quasi-monopolistic situation from the component manufacturers' viewpoint.



The European Engineering Industries Association

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
 Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
 Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

SEA Europe input on regulatory issues for possible future EU-US trade agreement

SEAEurope (Ships and maritime Equipment Association), would like to take the opportunity to raise the following shipbuilding specific regulatory issues and concerns in this public consultation.

1 Jones Act

The European shipbuilding industry has been effectively excluded from selling vessels to be used in American coastwise trades by the Jones Act and its subsequent revisions. Although some European marine equipment manufacturers have managed selling certain products to US shipbuilders, the Jones Act prevents them from offering integrated marine equipment systems more widely in the US because the use of foreign parts for ship construction is heavily restricted. Such protectionism is contrary to the overall liberalized trade intentions of the two trading partners.

The Jones Act (Merchant Marine Act of 1920, Section 27) requires all waterborne shipping between US ports be carried by vessels built in the US and owned and operated by Americans. The purpose of the Act is to ensure that the nation has a sufficient merchant marine and shipbuilding base to protect the nation's defense and commercial interest. Despite repeated efforts to break a deadlock on cabotage provisions, neither the OECD nor the World Trade Organization has been able to make progress in liberalizing domestic marine or air cabotage, although there has been considerable success in the freeing of international trade in marine services.

Since 2006 increased lobbying within the US has been undertaken to scrap the Jones Act. The major criticism is that the legislation has resulted in much higher building and fleet costs and consequently significantly declined competitiveness of the US merchant marine manufacturers and operators. US ship operators have an economic incentive to continue operating old vessels rather than replace them with newer, safer and more environmental friendly ships. As a result, most of the US merchant fleets are very old. For instance, the average age of Ro Ro in the US is 28 years, bulkers 31 years old, and containerships 29 years old. There is significant need to replace aging vessels. Take Ro Ro for example. In the US there are only 9 vessels in service, whereas in the world there are more than 1000 in service and within Europe, looking at the order book by June 2012 there are already 49. However, the upcoming new environmental regulations, i.e. SOx and NOx emission limit within the North American Emissions Control Area, will affect shipowners new building investment decisions.

The main supporters to this legislation are arguing without Jones Act all remaining US yards would be deconstructed or outsourced overseas resulting in the utter destruction of the US maritime industry. In turn this would bring higher costs for US

navy vessels and eventually require most navy ships meant for national defense to be built overseas as well.

There have been a few small cracks in the Jones Act fortress: for instance, a foreign-built cruise line was granted exclusive rights for passenger service in the Hawaiian Islands, because the two ships to be built for the route lay uncompleted in a bankrupt US yard. Precedent has been established, albeit on a temporary basis. There have also been exemptions for small passenger (under 12 persons) and rigid inflatable craft, Jones Act repairs (Peters, 2003) and a Presidential exemption for energy security.

SEA Europe understands that the debate on Jones Act is a historical and difficult one. Nevertheless, achieving certain compromise and opening certain market segments must be possible. For example, Europe could negotiate with the US for a liberalization program for passenger ships, Ro Ro and other complex specialized ship types where the demand for saver and greener design and performance is higher. This would bring both parties into a win-win situation. The US yards can still build standard ship types. The US operators will benefit from lower costs and better energy efficiency. The US consumers will be able to benefit from improved safety. The European shipbuilding industry would be able to enter a “new market” which could certainly help during this long crisis and crisis recovery period.

In addition to the Jones Act, the US Government has been providing large financial support to their shipbuilding industry.

2 Federal Ship Financing Program (Title XI Ship Financing)

The Federal Ship Financing Program (established pursuant to 46 USC Chapter 537) provides for a full faith and credit guarantee by the US Government of debt obligations issued by 1) US or foreign shipowners for the purpose of financing or refinancing either US flag vessels or eligible export vessels constructed, reconstructed or reconditioned in the US shipyards and 2) US shipyards for the purpose of financing advanced shipbuilding technology and modern shipbuilding technology of a privately owned general shipyard facility located in the US.

The amount of the obligations guaranteed by the Government is based on the “actual cost” of the vessels or the Technology as determined by the Secretary. Legislation permits guarantees for up to 87.5% of the actual cost of certain vessels whereas certain other vessels are limited to 75% financing. Amounts outstanding on existing Title XI obligations, or amounts outstanding on obligations not previously guaranteed and applicable to vessels may be refinanced up to the applicable financing level of the depreciated actual costs of the vessels but not exceeding the amount of the existing obligations being refinanced.

3 Small Shipyards Grants Program

The US Maritime Administration's Small Shipyard Grants Program provides equipment, pays for modernization and technical skills training for US maritime workforce and enable them to compete globally. Based on this program, in March 2012 9.98 Million USD in grants were approved to 15 small shipyards throughout the US.

SEA Europe would like to request for a review of the legitimacy of these state support programs and examine whether they are in line with WTO disciplines. Furthermore, the shipbuilding budget of the US Navy (75 billion USD for FY 2012 -16) is also really something to support the shipbuilding industry.

Enclosed: two articles showing an example of Title XI ship financing support.

Brussels 31st of October 2012

VALASTRO Silvia (TRADE)

From: José Ignacio Pradas <pradas-poveda@sercobe.es>
Sent: 12 November 2012 08:26
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Subject: SERCOBE: public consultation on the EU-USA trade negotiations
Attachments: PP_priorities_for_upcoming_EU-US_trade_and_economic_negotiations_oct12.pdf.pdf; Public_Consultation_EU-US_27Sep12_164730405451727112.pdf.pdf

Dear sirs,

SERCOBE is the Spanish National Association of Manufacturers of Capital Goods, being the business association of reference of an industry whose turnover in 2011 was of € 39.000 million and exports of € 31.000 million. At European level SERCOBE is member of CEOE (Spanish affiliate to BusinessEurope), while at European level SERCOBE is a ORGALIME member.

In the engineering industry, the launch of negotiations with the US with the aim to create an EU-USA free trade area can only be regarded as positive. However, the analysis of the current situation makes Spanish engineering companies to be afraid of the difficulties to get full advantage of a new FTA if certain obstacles to trade are not properly and timely removed. In the forthcoming negotiations, THE EU negotiators should arise an important and critical question: the dominant position held *de facto* by United Laboratories (known as UL) in the electrical equipment sector.

In order to get the UL certification, European companies have to depend on the availability and accuracy of the single provider: UL. Obtaining the UL certification involves high expenses and long lead times, what constitutes an important technical barrier preventing (not only) European companies from having fair access to the US market.

Therefore, SERCOBE has compiled quite a few number of records affected by the long procedures employed by UL to lease a certificate.

As member of ORGALIME SERCOBE is delighted to mention that we agree with the recent position paper related to EU-US trade relations.

Please find attached the draft position paper on the forthcoming EU-USA trade and economic negotiations.

In brief, Orgalime is the European Federation of Engineering Industries, and apart from being an active group of interests with regard to the common trade policy.


While globalization is evolving fast, it makes little sense to establish artificial barriers which distort competition. Some of the 400 affiliated Spanish companies (mostly SMEs) have experienced delays and huge costs for getting the UL certification. The abovementioned obstacles do mainly apply to electrical engineering equipment and devices, MV devices and transformers.

SERCOBE is fully aligned with ORGALIME position paper and we want the attached position paper. Even though the public consultation expired, we believe that by transmitting this offensive point the negotiation point for the very best of the European engineering industry, its jobs, competitiveness and growth.

In the event of requiring consultancy, please feel free to contact me.

Kind regards,

José Ignacio Pradas Poveda
 Director for Internal Market


Sercobe
 Spanish National Association of Manufacturers
 of Capital Goods
 c/ Jorge Juan, 47
 28001 Madrid (Spain)
 Tel. (+34) 91.435.7240 / 91.576.4796

Fax (+34) 91 577 0910
pradas-poveda@sercobe.es
www.sercobe.es



October 31, 2012

Re: USTR-2012-0028 - EU and U.S. call for input on regulatory issues for possible future trade agreement

The Business Roundtable (BRT), the TransAtlantic Business Dialogue (TABD,) and the European Round Table of Industrialists (ERT) are submitting the following comments jointly in response to USTR's request for comments in the above referenced matter. Our organizations represent chief executive officers and chairmen of leading U.S. and European companies. We are pleased that the U.S. Government and the European Commission (EC) have together agreed to seek public comments and encouraged associations to submit views jointly with their counterparts across the Atlantic, hence this joint submission.

In April, our three organizations issued the attached joint statement in strong support of the new High Level Working Group on Jobs and Growth (HLWG). In *Forging a Transatlantic Partnership for the 21st Century*, we recommended that the HLWG's objectives "should be ambitious in eliminating trade, investment and regulatory barriers and distortions in promoting regulatory coherence and should result in commercially relevant new-generation accords" in order to promote economic growth and job creation in the United States and Europe. A June 2005 report issued by the Organization for Economic Cooperation and Development (OECD) estimated that economic reforms in both the United States and the European Union (EU) related to the relaxation of regulations, tariffs, and restrictions on foreign direct investment could increase GDP per capita by up to 2.5 percent in the United States and up to 3 percent in Europe.¹ USTR's request for comments is especially timely and important because regulatory barriers are recognized as the most significant impediment to greater trade and investment between the United States and the EU.

In *Forging a Transatlantic Partnership for the 21st Century*, our three groups recognized that enhanced regulatory cooperation between the United States and the EU is central to strengthening and deepening our vibrant economic relationship. Promoting this goal will: (1) help U.S. and European businesses grow and create new jobs by eliminating unjustified regulatory differences and unnecessary red tape; (2) enhance the global competitiveness of our businesses by increasing productivity; (3) help our governments achieve regulatory objectives in

¹ OECD, "The Benefits of Liberalizing Product Markets and Reducing Barriers to International Trade and Investment: The Case of the United States and the European Union," *Economics Department Working Paper 432*, Paris, May 26, 2005.

a more effective and efficient manner; and (4) strengthen the ability of our governments to confront the disturbing rise of discriminatory standards in other countries.

Our joint statement also noted that achieving the core objectives of strengthening and deepening the U.S.-EU economic relationship “will require careful and thoughtful engagement by our governments and the private sector.” We want to commend the U.S. Government and the EC for jointly inviting U.S. and European industries to submit their views on how to promote greater transatlantic regulatory compatibility generally as well as asking for concrete ideas on how greater compatibility could be achieved in specific sectors. These collaborative requests are laying the foundation for the strong government-private sector partnership that will be the key to success in the hoped-for U.S.-EU negotiations on trade, investment and regulatory cooperation issues and in the future work of the Transatlantic Economic Council (TEC), the U.S.-EU High Level Regulatory Cooperation Forum (HLRCF), and the U.S.-EU High Level Working Group on Jobs and Growth (HLWG).

As you know, our organizations are general business groups whose members are chief executive officers and chairmen of leading U.S. and European companies representing a wide-range of economic sectors. Since sector-specific associations have the necessary experience and detailed information on what is needed to promote regulatory cooperation in their sectors, we have been encouraging these associations on both sides of the Atlantic to provide detailed sector-specific information to the U.S. Government and the EC, including responding to your request for comments, and to participate in the ongoing work of the TEC, the HLRCF and the HLWG. In particular, we are encouraging U.S. and European sector associations to work together to develop sector-specific recommendations to help shape and guide the hoped-for U.S.-EU negotiations on trade, investment and regulatory cooperation issues.

Regulatory and standards issues can by their nature often be more complicated than traditional trade and investment issues. They are often technically complicated as well as legally and politically complex because they involve public health, safety, welfare, and environmental protection issues. We are, therefore, committed to working with the U.S. Government and the EC to develop a negotiating framework and process for horizontal and sectoral regulatory issues which will be able to address effectively these unique issues and produce outcomes which will promote U.S.-EU regulatory cooperation.

Regulatory Consultation Process. In order to set the most constructive stage for U.S.-EU discussions during the hoped-for negotiations, we believe that the HLWG should immediately establish a consultation process under which the U.S. and EU: (1) would be required to notify each other of pending and new major proposed regulatory initiatives; and (2) would be able to discuss these initiatives in the context of the ongoing negotiations. This would not be a standstill requirement, but rather a process designed to inform the discussions and, to the extent possible,

to avoid serious differences which could undermine productive negotiations and the spirit of regulatory cooperation driving them.

High-Level Political Involvement. Overall, we believe that promoting regulatory cooperation will require the highest-level political engagement by both the United States and the EU. Senior level political engagement is essential to creating a viable working relationship in the negotiations between the trade negotiators and regulators and standard setters. It is also essential to establishing an effective and efficient working relationship with legislators who oversee the regulators and standards development bodies.

General Principles. We strongly support the fundamental principles outlined in the joint business community letter on regulatory cooperation, dated October 24, 2012, a copy of which is attached. In addition, the hoped-for negotiations on trade, investment and regulatory cooperation issues should recognize that there are sound principles that can be applied to developing smart regulation that are common to all sectors to ensure that regulations are cost-effective, grounded in the most advanced scientific knowledge available, and are the most efficient and effective means to achieve objectives. Regulatory processes, including government review and management of agency rulemaking, should be open to public scrutiny, regulations should be reviewed regularly for the purposes of determining whether they should be reformed or discontinued, and paperwork burdens should be considered and reduced where possible.

Ripe, Riper, Ripest. In addition to negotiating horizontal and sectoral regulatory provisions which would establish a constructive and dynamic system for regulatory cooperation, we believe the U.S. and EU need to continue to push forward aggressively with other initiatives to address regulatory issues for specific sectors. In doing so the U.S. and EU will need to take into consideration, for example, which sectors might be better positioned for more immediate action, and whether the specific sector issues in question would be addressed more effectively and expeditiously in the HLWG, the TEC and/or the HLRCF.

Longer-Term Regulatory Issues. Finally, it is important to recognize that some regulatory barriers and distortions may be so complicated or so deeply embedded in our respective legal, policy and political structures that greater transatlantic regulatory compatibility may not be immediately achievable. Instead of simply setting these issues aside, the negotiations should be used to find new ways to reinforce existing mechanisms like the TEC and the HLRCF and consider new initiatives for addressing these issues on an ongoing basis.

Thank you for the opportunity to provide comments on these important issues. We look forward to working with you and your EU colleagues to ensure that the HLWG succeeds in promoting stronger economic growth on a sustained basis and creating new jobs in both the United States and Europe. We hope next steps will include the HLWG's recommendation in its

final report due later this year that the U.S. and EU launch ambitious and comprehensive trade, investment, and regulatory cooperation negotiations next year.

Sincerely,



Governor Engler
President
Business Roundtable



Kathryn Hauser
U.S. Executive Director
TABD



Brian Ager
Secretary General
ERT

63

VALASTRO Silvia (TRADE)

From: Claire Layton <clayton@tabd.com>
Sent: 31 October 2012 17:31
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: DEMARTY Jean-Luc (TRADE); CALLEJA CRESPO Daniel (ENTR); GARCIA BERCERO Ignacio (TRADE); PERREAU DE PINNINCK Fernando (TRADE); LEVIE Damien (TRADE); EMBERGER Geraldine (TRADE); NIETO HERNANDEZ Esther (TRADE); ROELAND Christophe (ENTR); Hendrike Kuehl; Kathryn Hauser; Emanuel Adam; Thomas, David; Roeland Van der Stappen
Subject: BRT-TABD-ERT Submission to EU and US call for input on regulatory issues for possible future trade agreement
Attachments: TABD-BRT-ERT Response to US-EU Request for Regulatory Comments 311012.pdf; BRT-TABD-ERT Vision for TAP Apr 2012.pdf; Transatlantic Reg. Coop Assoc. Ltr - 10-24-2012.pdf

Please find a joint submission attached by the BRT-TABD-ERT on regulatory issues for a possible future trade agreement as well as 2 additional documents that are referenced in the submission.

With kind regards,

Claire Layton
U.S. Administrator

TransAtlantic Business Dialogue
1717 Pennsylvania Avenue, NW
Suite 1025
Washington, DC 20006
Tel: 202.559.9298
Fax: 202.559.9297

October 24, 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: US-EU Regulatory Compatibility

We, the undersigned associations, write to strongly encourage the U.S.-EU High Level Working Group on Jobs and Growth (Working Group) to endorse ambitious and well-developed regulatory cooperation provisions as part of any recommended negotiation that seeks a high-standard transatlantic trade and investment agreement. Strengthening economic ties and enhancing transatlantic regulatory cooperation through an agreement that would include both goods and services, including financial services, are essential to eliminating unnecessary regulatory divergence that may act as a drag on economic growth and job creation.

U.S. and EU regulators already cooperate extensively with one another, both directly and in the context of broader formal arrangements such as the G-20 dialogue, the Transatlantic Economic Council (TEC), the U.S.-EU High Level Regulatory Cooperation Forum (HLRCF), and the U.S.-EU Financial Markets Regulatory Dialogue. However, these arrangements can be made much more effective and should include enhanced opportunities for dialogue with stakeholders. Any agreement should enhance current efforts and develop the regulatory cooperation mechanisms needed to unlock the true potential of an agreement.

Such provisions should comprehensively and ambitiously address traditional technical barriers to trade and sanitary/phyto-sanitary issues. These provisions should also expressly encourage regulators to work together to reduce and eliminate duplicative and inconsistent measures in existing regulations and where appropriate utilize recognition arrangements. In addition, the agreement should work to limit future unwanted regulatory divergence by promoting a better understanding of the impact significant regulations may have on the transatlantic market and facilitate information sharing, which will ensure regulatory decisions when appropriate, reflect the marketplace, are fact based, grounded in sound science, and undergo thorough regulatory and cost-benefit analysis.

We thank you for your consideration and look forward to the opportunity to assist the Working Group in developing and implementing regulatory cooperation provisions that maximize benefits to stakeholders, the government and the public.

Advanced Medical Technology Association
American Automotive Policy Council
American Chemistry Council
American Council of Life Insurers
Association of British Insurers
Association for Financial Markets in Europe
Biotechnology Industry Organization
BUSINESSEUROPE
Business Roundtable
Coalition of Service Industries
The Council of Insurance Agents and Brokers
Emergency Committee for American Trade
European-American Business Council
European Federation of Pharmaceutical Industries and Associations
European Chemical Industry Council
Financial Services Roundtable
Insurance Europe
Medical Imaging Technology Alliance
National Association of Manufacturers
National Foreign Trade Council
National Electrical Manufacturers Association
Personal Care Products Council
Pharmaceutical Research and Manufacturers of America
Securities Industry and Financial Markets Association
TheCityUK
The TransAtlantic Business Dialogue
Transatlantic Coalition on Financial Regulation
U.S. Chamber of Commerce
United States Council for International Business



October 31, 2012

Re: USTR-2012-0028 - EU and U.S. call for input on regulatory issues for possible future trade agreement

The Business Roundtable (BRT), the TransAtlantic Business Dialogue (TABD,) and the European Round Table of Industrialists (ERT) are submitting the following comments jointly in response to USTR's request for comments in the above referenced matter. Our organizations represent chief executive officers and chairmen of leading U.S. and European companies. We are pleased that the U.S. Government and the European Commission (EC) have together agreed to seek public comments and encouraged associations to submit views jointly with their counterparts across the Atlantic, hence this joint submission.

In April, our three organizations issued the attached joint statement in strong support of the new High Level Working Group on Jobs and Growth (HLWG). In *Forging a Transatlantic Partnership for the 21st Century*, we recommended that the HLWG's objectives "should be ambitious in eliminating trade, investment and regulatory barriers and distortions in promoting regulatory coherence and should result in commercially relevant new-generation accords" in order to promote economic growth and job creation in the United States and Europe. A June 2005 report issued by the Organization for Economic Cooperation and Development (OECD) estimated that economic reforms in both the United States and the European Union (EU) related to the relaxation of regulations, tariffs, and restrictions on foreign direct investment could increase GDP per capita by up to 2.5 percent in the United States and up to 3 percent in Europe.¹ USTR's request for comments is especially timely and important because regulatory barriers are recognized as the most significant impediment to greater trade and investment between the United States and the EU.

In *Forging a Transatlantic Partnership for the 21st Century*, our three groups recognized that enhanced regulatory cooperation between the United States and the EU is central to strengthening and deepening our vibrant economic relationship. Promoting this goal will: (1) help U.S. and European businesses grow and create new jobs by eliminating unjustified regulatory differences and unnecessary red tape; (2) enhance the global competitiveness of our businesses by increasing productivity; (3) help our governments achieve regulatory objectives in

¹ OECD, "The Benefits of Liberalizing Product Markets and Reducing Barriers to International Trade and Investment: The Case of the United States and the European Union," *Economics Department Working Paper 432*, Paris, May 26, 2005.

a more effective and efficient manner; and (4) strengthen the ability of our governments to confront the disturbing rise of discriminatory standards in other countries.

Our joint statement also noted that achieving the core objectives of strengthening and deepening the U.S.-EU economic relationship “will require careful and thoughtful engagement by our governments and the private sector.” We want to commend the U.S. Government and the EC for jointly inviting U.S. and European industries to submit their views on how to promote greater transatlantic regulatory compatibility generally as well as asking for concrete ideas on how greater compatibility could be achieved in specific sectors. These collaborative requests are laying the foundation for the strong government-private sector partnership that will be the key to success in the hoped-for U.S.-EU negotiations on trade, investment and regulatory cooperation issues and in the future work of the Transatlantic Economic Council (TEC), the U.S.-EU High Level Regulatory Cooperation Forum (HLRCF), and the U.S.-EU High Level Working Group on Jobs and Growth (HLWG).

As you know, our organizations are general business groups whose members are chief executive officers and chairmen of leading U.S. and European companies representing a wide-range of economic sectors. Since sector-specific associations have the necessary experience and detailed information on what is needed to promote regulatory cooperation in their sectors, we have been encouraging these associations on both sides of the Atlantic to provide detailed sector-specific information to the U.S. Government and the EC, including responding to your request for comments, and to participate in the ongoing work of the TEC, the HLRCF and the HLWG. In particular, we are encouraging U.S. and European sector associations to work together to develop sector-specific recommendations to help shape and guide the hoped-for U.S.-EU negotiations on trade, investment and regulatory cooperation issues.

Regulatory and standards issues can by their nature often be more complicated than traditional trade and investment issues. They are often technically complicated as well as legally and politically complex because they involve public health, safety, welfare, and environmental protection issues. We are, therefore, committed to working with the U.S. Government and the EC to develop a negotiating framework and process for horizontal and sectoral regulatory issues which will be able to address effectively these unique issues and produce outcomes which will promote U.S.-EU regulatory cooperation.

Regulatory Consultation Process. In order to set the most constructive stage for U.S.-EU discussions during the hoped-for negotiations, we believe that the HLWG should immediately establish a consultation process under which the U.S. and EU: (1) would be required to notify each other of pending and new major proposed regulatory initiatives; and (2) would be able to discuss these initiatives in the context of the ongoing negotiations. This would not be a standstill requirement, but rather a process designed to inform the discussions and, to the extent possible,

to avoid serious differences which could undermine productive negotiations and the spirit of regulatory cooperation driving them.

High-Level Political Involvement. Overall, we believe that promoting regulatory cooperation will require the highest-level political engagement by both the United States and the EU. Senior level political engagement is essential to creating a viable working relationship in the negotiations between the trade negotiators and regulators and standard setters. It is also essential to establishing an effective and efficient working relationship with legislators who oversee the regulators and standards development bodies.

General Principles. We strongly support the fundamental principles outlined in the joint business community letter on regulatory cooperation, dated October 24, 2012, a copy of which is attached. In addition, the hoped-for negotiations on trade, investment and regulatory cooperation issues should recognize that there are sound principles that can be applied to developing smart regulation that are common to all sectors to ensure that regulations are cost-effective, grounded in the most advanced scientific knowledge available, and are the most efficient and effective means to achieve objectives. Regulatory processes, including government review and management of agency rulemaking, should be open to public scrutiny, regulations should be reviewed regularly for the purposes of determining whether they should be reformed or discontinued, and paperwork burdens should be considered and reduced where possible.

Ripe, Riper, Ripest. In addition to negotiating horizontal and sectoral regulatory provisions which would establish a constructive and dynamic system for regulatory cooperation, we believe the U.S. and EU need to continue to push forward aggressively with other initiatives to address regulatory issues for specific sectors. In doing so the U.S. and EU will need to take into consideration, for example, which sectors might be better positioned for more immediate action, and whether the specific sector issues in question would be addressed more effectively and expeditiously in the HLWG, the TEC and/or the HLRCF.

Longer-Term Regulatory Issues. Finally, it is important to recognize that some regulatory barriers and distortions may be so complicated or so deeply embedded in our respective legal, policy and political structures that greater transatlantic regulatory compatibility may not be immediately achievable. Instead of simply setting these issues aside, the negotiations should be used to find new ways to reinforce existing mechanisms like the TEC and the HLRCF and consider new initiatives for addressing these issues on an ongoing basis.

Thank you for the opportunity to provide comments on these important issues. We look forward to working with you and your EU colleagues to ensure that the HLWG succeeds in promoting stronger economic growth on a sustained basis and creating new jobs in both the United States and Europe. We hope next steps will include the HLWG's recommendation in its

final report due later this year that the U.S. and EU launch ambitious and comprehensive trade, investment, and regulatory cooperation negotiations next year.

Sincerely,



Governor Engler
President
Business Roundtable



Kathryn Hauser
U.S. Executive Director
TABD



Brian Ager
Secretary General
ERT



**Business
RoundtableSM**



**TRANS ATLANTIC
BUSINESS DIALOGUE**



ERT

April 18, 2012

Forging a Transatlantic Partnership for the 21st Century

*Joint Statement by Business Roundtable, the TransAtlantic Business Dialogue and
the European Round Table of Industrialists¹*

Overview of a New Transatlantic Partnership Vision

We welcome the new U.S.-EU High Level Working Group on Jobs and Growth and the U.S. and EU government leaders' declared intent for it to consider the full range of trade and investment measures that could be taken to revitalize and intensify our strong economic relationship. We are concerned, however, that absent a clear and compelling vision of a more strategic, dynamic and forward-looking partnership, the effort will not fulfill its promise.

We believe the vision should be to develop a new Transatlantic Partnership (TAP) to deepen the U.S.-EU economic relationship and to strengthen the international economic system and its rules and standards, thereby supporting innovation, economic growth, and job creation in the United States and the EU and around the world. This is not a time for piecemeal efforts; it is a time for transformative action and leadership. To further this vision, the effort should focus on, and integrate effectively, three core objectives: (1) renewing and opening more deeply the 21st Century transatlantic market; (2) positioning our partnership so we can better both compete with and engage third countries on the fundamental rules underpinning 21st Century trade and investment; and (3) strengthening the WTO and deepening the multilateral commitment to open markets.

As CEOs and chairmen of businesses engaged across the global economy, we need nothing less. If we are to galvanize our companies and sectors to position our global ambitions around the opportunity represented by the new U.S.-EU High Level Working Group on Jobs and Growth, then it is self-evident that the strategic vision and structure will need to serve as a global template.

As business leaders on both sides of the Atlantic, we believe the renewal and further opening of the transatlantic market is important to reenergizing our economies and the global economy. We welcome all serious efforts to that end, and offer our support in realizing that goal. But in today's global economy we cannot afford to limit our ambition to a standard bilateral free trade agreement. On its own, such an exercise is insufficient to meet the broader economic challenges we face. This transatlantic partnership should advance an agenda for jobs and growth that opens transatlantic markets while simultaneously creating a dynamic environment to promote international cooperation to open global markets. Efforts to open transatlantic markets must be tied to joint efforts to strengthen the ground rules of the international economic system and to engage the emerging growth markets in a common effort to extend the benefits of open markets to their citizens and companies.

¹ Business Roundtable, the TransAtlantic Business Dialogue and the European Round Table of Industrialists would like to acknowledge the assistance of Daniel S. Hamilton, Ph.D. in helping prepare this paper. Mr. Hamilton is the Executive Director of the Johns Hopkins University Center for Transatlantic Relations at The Paul H. Nitze School of Advanced International Studies in Washington, DC.

Why a Transatlantic Partnership and Why Now?

Even with the rise of other economic powers, including the emerging growth markets, the United States and the EU remain the fulcrum of the world economy, each other's most important and profitable market and source of on-shored jobs, each other's most important strategic partner, and the driving force in the multilateral economic system — when we work in concert.

The notion is mistaken that we can “go it alone” in trying to convince other countries to reject protectionist trade policies, forego discriminatory industrial and regulatory policies, and provide adequate and effective intellectual property protection. This can also lead to serious missed policy opportunities for the United States and the EU to raise the bar in terms of setting international norms and standards. Strengthening transatlantic bonds is important not only in terms of how Europeans and Americans relate to each other, but how we can harness the potential of the transatlantic partnership to open markets in other countries, especially the emerging growth markets, and strengthen the international economic system. In fact, the stronger the bonds among core market economies like the United States and the EU, the better our chances of being able to include rising economic powers as responsible stakeholders within an open international economic system.

Despite its strength and potential, the U.S.-EU relationship punches below its weight and fails to capitalize on significant opportunities for our citizens, companies, workers, consumers and the multilateral economic system we, together with many other partners, helped bring to life.

Core Elements of a New and More Dynamic Transatlantic Partnership

We believe the vision for a Transatlantic Partnership (TAP) must encompass three core, mutually-reinforcing objectives. There will be a natural inclination to do what we all know best—focus quickly on the granular elements of either a standard bilateral free trade agreement or targeted sectoral trade, investment and regulatory negotiations. Achieving the core objectives will require careful and thoughtful engagement by our governments and private sectors. The U.S.-EU High Level Working Group on Jobs and Growth has created a unique opportunity for the United States and the EU to revitalize and reshape their relationship on both a bilateral and global scale; and this opportunity should not be wasted.

First and foremost, we must renew and more deeply open the 21st Century Transatlantic Market with ambitious targets. The goal of a renewed and open transatlantic market should not be just another “free trade agreement;” it should be a more ambitious and relevant new-generation accord, rooted in the distinctive nature and potential of the transatlantic partnership. In addition to being grounded in essential principles of WTO-consistency, transparency, and non-discrimination among the parties, it should advance synergistic strategies across a range of areas, from removing tariff and non-tariff barriers to transatlantic trade in industrial and agricultural goods and services, removing restrictions on job-creating investments, further opening of the public procurement market, overcoming regulatory obstacles, boosting innovation, encouraging the flow of people and talent across the transatlantic space to addressing emerging 21st Century issues like facilitating cross-border data flows which have become essential to global manufacturing and services operations.

- *The initiatives need to focus on achieving each of the core objectives outlined in this paper to the maximum extent and as quickly as possible.*
- *The initiatives should be ambitious in eliminating trade, investment and regulatory barriers and distortions in promoting regulatory coherence and should result in commercially relevant new-generation accords.*

The framework needs to recognize that the U.S. and EU economies are so integrated that some of the few remaining barriers and distortions are deeply embedded in our respective legal, policy and political structures and their resolution may not necessarily fit effectively into the negotiating structure of a new transatlantic agreement. Such hurdles must be recognized at an early stage and addressed in a positive way to ensure that the momentum of trade liberalization is maintained. The U.S.-EU High-Level Working Group on Jobs and Growth should also integrate into its recommendations how the United States and the EU might use other mechanisms like the Transatlantic Economic Council (TEC) and how the EU and the United States can engage more effectively other key stakeholders, including legislators, regulators and standards setters, to move forward on issues that will require more extensive work.

Second, we must reposition our partnership so we can better engage with third countries on the economic ground rules underpinning the multilateral system. Efforts to open transatlantic markets and lift and align transatlantic standards and regulatory regimes can – and must – drive broader international cooperation. The stronger our bilateral convergence, the more seriously third countries will respond and the greater the likelihood of making tangible progress in opening markets and ensuring a rules-based approach and norms. This is an opportune moment for such an agenda. The multilateral system administered by the WTO is under challenge, especially by emerging growth markets that have benefited substantially from the system. A number of rapidly emerging countries do not share the core principles or basic structures that underpin open rules-based commerce, and are now showing no real interest in new market opening initiatives. As a result, the global economy is drifting dangerously towards the use of national discriminatory trade, regulatory and investment practices.

The United States and the EU have used the TEC process to coordinate and align policy responses to certain actions taken by third countries that discriminate against transatlantic businesses. This joint effort has proven successful and should continue on a parallel track as the U.S.-EU High-Level Working Group on Jobs and Growth focuses on its work. In this regard, the United States and the EU must pioneer more dynamic and effective forms of transatlantic collaboration that provide new opportunities to reach out to the emerging growth markets to open their markets, to lift international standards, and to strengthen multilateral rules. Given the size and scope of the transatlantic economy, standards negotiated by the United States and the EU can quickly become the benchmark for inclusive regional and ultimately global models, reducing the likelihood that others will impose more stringent, protectionist requirements or discriminatory industrial and regulatory policies for either products or services.

The goal is not to build an Atlantic Fortress, but instead to pave the way for sustainable economic growth in the global marketplace. Europeans and Americans certainly share an interest in extending prosperity through open markets. Because of this, Europeans and Americans should forge ahead, identifying points of agreement on the elimination of traditional trade and investment barriers on regulatory norms and standards where they can, and using such agreement to engage third countries. Our chief goal should in fact be to make broader institutions work much more effectively, by seeking general agreement on goals and purpose before engaging in larger fora, thus supplementing rather than supplanting such bodies.

- *The new U.S.-EU High-Level Working Group on Jobs and Growth needs to factor into its planning the important fact that the United States and the EU have concluded many bilateral free trade agreements and are moving forward with new agreements with a special emphasis on modernizing them to tackle pressing 21st Century issues such as trans-border data flows, discriminatory industrial policies and state-owned enterprises. The United States is pursuing the Trans Pacific Partnership (TPP), while the EU is concluding a Comprehensive Economic and Trade Agreement with Canada, has ongoing negotiations with India, Mercosur and others, including most recently with Japan.*

- *In this growing web of economic integration, there is a glaring hole the U.S.-EU High-Level Working Group on Jobs and Growth has to recognize and develop a strategy for filling. The free trade agreements negotiated by the United States and the EU overlap considerably. Under these circumstances, the U.S.-EU High-Level Working Group needs to develop a negotiating framework that will promote alignment of these agreements and an opportunity for new countries to join in the newer arrangement.*
- *Alignment, such as reconciling different rules of origin, would enhance the economic growth and job creation benefits of the agreements by reducing transaction costs and the burden of complying with different sets of rules that companies and their workers must navigate.*
- *The alignment process could also create a dynamic environment in which it might be possible to draw some of the emerging growth countries who do not have free trade agreements with either the EU or the United States into an agreement. This dynamic appears to be working in the TPP where Malaysia and Vietnam have already become parties to the negotiations, and Japan, Canada and Mexico have now all asked to join the negotiations. Given the unfortunate deadlock in the WTO Doha negotiations, creating such a new dynamic could be a major boost to creating a stronger and broader commitment to open markets.*

Third, we must strengthen and deepen the commitment in the WTO to open markets and extend the rules-based multilateral system to include new areas of commercial opportunity. Commercial barriers must come down not only across the Atlantic, but around the world too. We remain committed to the multilateral trade liberalization agenda under the auspices of the WTO. Yet we should also explore opportunities that give us more viable options than moving the global economy ahead in lockstep or not at all.

In addition, the United States and the EU should work together and with other like-minded partners to extend the rules-based multilateral system to new areas of endeavor. Most new cooperative economic arrangements today address issues beyond traditional “at the border” barriers to trade in goods and services as originally formulated by the GATT and GATS. New guidelines are needed to apply such fundamental WTO principles as transparency, non-discrimination between the parties, and national treatment to international economic transactions ranging far beyond the traditional trade agenda.

Those who worry that an ambitious Transatlantic Partnership could threaten the multilateral economic system should not be concerned by this new transatlantic initiative. They should consider that the opposite may be true. In fact, how the United States and Europe deal with the interrelated challenges and opportunities posed by bilateral issues, rising powers, and overlapping networks of FTAs could go far to shape the multilateral agenda for a new age and ultimately strengthen the multilateral system, especially the WTO.

In this sense, transatlantic markets have become the laboratory for the international trading system; many transatlantic issues cannot be addressed by multilateral efforts alone. That is why the “multilateral versus transatlantic” dichotomy is a false choice. The United States and the EU should advance on both fronts simultaneously: push multilateral liberalization and press transatlantic market-opening initiatives in areas not yet covered by multilateral agreements. The alternative to this WTO+ agenda is not drift; it is growing protectionism, U.S.-EU rivalry in third markets, and the triumph of lowest-common-denominator standards for the health and safety of our people. The absence of common rules and procedures weakens the leverage of our two regions to ensure that high standards prevail.

- *The U.S.-EU High-Level Working Group on Jobs and Growth should propose ideas on how existing and future U.S. and EU agreements could be used to strengthen and deepen the WTO's commitment to open and non-discriminatory markets.*
- *For example, consideration should be given to using these agreements to develop non-binding "best practices," like the EU-U.S. ICT Principles, which could be promoted within the WTO to guide countries on how to create a more effective trade, investment and regulatory environment for growth and job creation.*
- *In addition, the United States and the EU should explore how they could use the TAP and TPP to promote plurilateral negotiations under the auspices of the WTO whereby non-party WTO members could dock to either or both of these agreements or work together to merge these and/or other high standard bilateral and regional trade agreements.*
- *Ultimately, the goal would be to try to use these types of initiatives to reinvigorate the overall commitment in the WTO to negotiate new multilateral agreements that are more relevant to the global economy in the 21st Century.*

Conclusion

The U.S.-EU relationship remains the foundation of the global economy and the essential underpinning of a strong, rules-based international economic order. We literally cannot afford to neglect it. Instead, we need to put our partnership to work – to open our markets; to engage the emerging growth countries; and to strengthen global rules. A 21st Century Transatlantic Partnership is within our grasp, but it is not the relationship we have today. Given the challenges we face, such a partnership is urgent. We are committed to working with U.S. and EU government leaders and others in the business community to create a new and more effective transatlantic partnership that supports economic growth and job creation.



Business Roundtable (BRT) is an association of chief executive officers of leading U.S. companies with over \$6 trillion in annual revenues and more than 14 million employees. BRT member companies comprise nearly a third of the total value of the U.S. stock market and invest more than \$150 billion annually in research and development – nearly half of all private U.S. R&D spending. Our companies pay \$163 billion in dividends to shareholders and generate an estimated \$420 billion in sales for small and medium-sized businesses annually. BRT companies give nearly \$9 billion a year in combined charitable contributions.

Please visit us at www.brt.org, check us out on [Facebook](#) and [LinkedIn](#), and follow us on [Twitter](#).



The TransAtlantic Business Dialogue (TABD) is the official dialogue between transatlantic business and U.S. Cabinet Secretaries and EU Commissioners. Participating chief executives and chairmen from leading American and European companies discuss transatlantic business issues, share recommendations for action, and engage in a dialogue with the U.S. Government and EU Commission on the future of the transatlantic economic relationship and engagement with third countries. TABD is also the official business advisor to the Transatlantic Economic Council (TEC).

Please visit www.tabd.com for more information.



The European Round Table (ERT) of Industrialists brings together around 50 chief executives and chairmen of major multinational companies of European parentage. Companies of ERT Members cover a wide range of industry sectors. Their combined turnover exceeds €1,000 billion and they employ 6.6 million people in Europe.

Please visit www.ert.eu for more information.