LA ROVERE Annalisa (GROW)

From: CAB TAJANI ARCHIVES
Sent: 12 May 2014 14:01
To: CAB BARNIER ARCHIVES
Cc: [redacted](CAB-TAJANI)
Subject: Letter ORGALIME to M. Barnier 08/05/2014 - Orgalime position paper on the Transatlantic Trade and Investment Partnership
Attachments: Orgalime_TTIP_paper.pdf; Orgalime_Letter_TTIP_MrBarnier.pdf

Dear colleagues,

Did you already register this letter to M. Barnier dated 08/015/02/2014 on TTIP?

If yes, thank you for putting ve_ca.7.cad in info.
If not, do you want me to register it?

Thank you
Best regards
[redacted]

From: [redacted] (CAB-TAJANI)
Sent: Monday, May 12, 2014 12:38 PM
To: CAB TAJANI ARCHIVES
Cc: [redacted](CAB-TAJANI)
Subject: FW: Orgalime position paper on the Transatlantic Trade and Investment Partnership

FB = CF

From: Andre Jackie (AEJ) [mailto:jackie.andre@orgalime.org]
Sent: Thursday, May 08, 2014 5:24 PM
To: CANGA FANO Diego (CAB-TAJANI); BENINI Fabrizia (CAB-TAJANI); BALDINATO Massimo (CAB-TAJANI); KUCK Sebastian (CAB-TAJANI); PANELLA Lauro (CAB-TAJANI)
Subject: Orgalime position paper on the Transatlantic Trade and Investment Partnership

To: Mr Canga Fano, Ms Benini, Messrs Baldinato, Kuck, Panella

Orgalime position paper on the Transatlantic Trade and Investment Partnership

Dear Madam, Dear Sir,

Please find enclosed a copy of our letter and position paper sent to Commissioner Barnier concerning the Transatlantic Trade and Investment Partnership.

Yours sincerely,

Adrian Harris
Director General

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ORGALIME

Position Paper

Brussels, 8 May 2014

The Transatlantic Trade and Investment Partnership negotiations - a way forward

EXECUTIVE SUMMARY

The EU and US have decided to take their economic relationship to a higher level by agreeing to launch negotiations on a transatlantic trade and investment partnership (TTIP). Orgalime is a supporter of the TTIP negotiations and in this updated position paper we further explain our views on tariffs on industrial goods, non-tariff barriers to trade (NTBs), regulatory and other issues. We elaborate on the importance of procedural and regulatory transparency on both EU and US side, on the burden of unnecessary costs suffered by companies in the US due to the lack of mutual recognition of test results among NRTLs, on the need for freer access to public procurement contracts (at both state and federal level) as well as on possible solutions in the field of dual-use goods.

Today there is much focus on the regulatory component of the agreement, and in this respect on standardisation, and conformity assessment procedures. In response to that, Orgalime provides very detailed explanations on the technical barriers to trade encountered by European engineering companies and concrete recommendations on how to solve these. Orgalime considers that an ambitious agreement on regulatory conditions for placing products on the market can save costs for manufacturers and boost both trade and investments on both sides of the Atlantic. TTIP negotiations are an opportunity to improve technical cooperation by minimising as far as possible the existing differences in the respective regulations and by reducing the number of competitive standards for the same product. We emphasise the need to maintain support to ISO, IEC and ITU as the preferred platforms to ensure compatible standards not only between the EU and US but also with other important trading partners of both sides.

If an EU–US agreement is reached, it would be an important step towards increasing the transatlantic trade flows which today, for our industries, already stand at 67 billion euro and have room to grow. It is therefore essential, in our view, that the focus of negotiators should be on reaching a high quality agreement which not only deals with the so-called "low hanging fruit" but also sets the basis for progress on regulatory convergence for the years to come and the mechanisms to achieve this. Quality rather than speed must be the driver for the TTIP agreement.

Orgalime, the European Engineering Industries Association, speaks for 38 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2012 accounted for some €1,840 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

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1. INTRODUCTION

The US is one of the largest markets for European mechanical, electrical and electronics engineering exports. In 2012, the export volume of Orgalime products to the United States accounted for 33% of the total EU exports to the USA. Trade in the other direction is also very significant. Total trade amounts to some 150-160 billion Euro.

Trade relations between the EU and the US are also reflected in the mutual direct investment, and the US is one of the largest markets in terms of outward direct investment made by the European engineering industry outside of Europe.

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.

In February 2013 the EU and US decided to take their economic relationship to a higher level by agreeing to launch negotiations on a transatlantic trade and investment agreement, named later TTIP. Until now, the negotiations have reached the 5th round (May 2014). Orgalime believes there is a great potential to strengthen further EU-US trade and investment relations to support mutually beneficial job creation, economic growth, and international competitiveness, and we stand ready to assist negotiators in finding ways to increase trade and investment between the two regions.

Orgalime considers that an ambitious agreement on regulatory conditions for placing products on the market can save costs of manufacturers and boost both trade and investments on both sides of the Atlantic.

We believe that such a regulatory dialogue should start by identifying common regulatory objectives to help approximate legal requirements in the electrical and mechanical engineering fields. This step is in our view necessary for standards to be recognised as globally relevant, as these would effectively respond to regulatory needs and market needs both in the US and in the EU. Co-operation within the UNECE has shown that it works for ICT equipment (GSM, peripherals, WLAN, PSTN, Bluetooth...) and equipment intended for use in explosive atmospheres (ATEX). Thereby, it would increase the regulatory influence of the EU and US on third markets, facilitating the circulation of our products in these markets.

It is essential, in our view, that the focus of negotiators on both sides of the Atlantic should be on reaching a high quality agreement which not only deals with the "low hanging fruit"" but also sets the basis for progress on regulatory convergence over time and the mechanisms to achieve this. Quality rather than speed must be driver for TTIP.

The present paper builds on past Orgalime positions that can be consulted at www.orgalime.org [1]

[1] *29 May 2013 - Orgalime position paper on the Negotiations of the comprehensive Transatlantic Trade and Investment Partnership*
5 October 2012 - Orgalime priorities for the upcoming EU-US trade and economic negotiations
24 October 2011 - EU manufacturers suffer from malfunctioning of the US certification market: potential abuse of dominant position

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regulatory convergence forces companies to invest time in diverging procedures in order to demonstrate compliance. This constitutes for companies, especially small and medium-sized companies, an extra cost and a barrier to trade.

In Orgalime's view the EU-US agreement should develop processes and mechanisms to achieve regulatory coherence on a global level. It is difficult to revise the regulatory acquis of placing products on the market in the framework of a trade agreement. However, negotiators and authorities should face this situation as an opportunity in which industry could adopt procedures that would ensure coherence and streamlining of requirements in the future legislation. This could include: early consultations between the trade partners whenever legislation is to be adopted or reviewed, including an estimation of the impact on trade before proposing any regulatory change.

This can be strengthened by an institutional process and procedural requirements for a "regulator to regulator" cooperation after negotiations have been concluded, in order to establish a so called "living agreement".

Moreover, the issue of transparency (transparent, open and predictable procedural requirements) should be at the heart of TTIP agreement. The two partners should share data with each other that would enable regulatory comparisons, more solid impact assessments and mutual compliance.

We provide hereafter in an annex to the present position concrete analysis of areas of regulatory divergence, with suggestions on how progress towards convergence could be made.

Standards

The EU and the US have different standardisation models, which have been shaped over many decades taking into account each side's history, culture and values.

Nevertheless, there is interest of the European business community, as well as among regulators, to avoid incoherency at international level and unnecessary duplication of work.

Unfortunately, until now the US attempts to align international and US standards – are still at the very beginning. As an example, we witness that only some 134 IEC standards have been implemented in the US. At the same time, in Europe, more than 4000 standards from IEC have been implemented. This can be partially attributed to the existing agreements, ISO/CEN Vienna agreement and the IEC/CENELEC Dresden agreement, to avoid duplication of work and to coordinate better.

TTIP negotiations should aim at overcoming this discrepancy. To date, we see it as achievable via regional agreements with ISO and IEC that already constitute an international platform open to both European and American stakeholders in an open, transparent and democratic manner.

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monitor new standardisation work items initiated by American SDOs, spreading scarce resources over multiple chess boards. This also results in the need to purchase standards from more sources which could become increasingly complex and costly.

The solution could be to establish a transparent system detailing how legislation and standards interact, including notifications of planned developments. The European Standardisation System already largely meets this need for transparency. It is our view that the US Administration should introduce a similar level of transparency and predictability to the best achievable level within the existing framework, especially for standards that specify the applicable conformity assessment procedure.

In the short term, we suggest that the US establishes a single source of information – in form or a portal - which should list in a transparent way the applicable legislation, all accredited SDOs, their relation to applicable Federal or State legislation per industrial sector, where to apply for active participation in standardisation work, and where to buy available standards.

In the n a longer term, the US and EU regulators should commit that only standards developed in close connection with IEC and ISO could be used for supporting compliance with both EU and US legislation. An informative annex to the US standard and to the corresponding EU standard could state, which specification in the standard refers to the safety or regulatory provisions of the US or the EU.

Mutual Recognition of conformity assessment procedures

Direct mutual recognition of conformity assessments procedures cannot be effectively implemented at the present time without significant disadvantages, owing to the completely different regulatory philosophies in the EU and the US. However, we believe a "living agreement" can gradually produce solutions acceptable to both sides.

Orgalime industries value the European system whereby EU authorities rely on the manufacturers' declaration for a wide range of products and require third party conformity assessment reports or certificates for only certain groups of products, for example dangerous machinery. This is a cornerstone of the European industry's competitiveness, as it saves time and costs to European manufacturers. It is equally a trade-facilitation measure for importers of products from US or other origins. For the US, such mechanisms will improve the efficiency of markets too, as testing costs will decline.

Therefore, it is essential to ensure that the liberal nature of the successful European market access system is not jeopardised or abandoned in a streamlining process of the EU and US regulatory systems.

embargos and in regular export controls), supplier and performance restrictions directly aimed at extra-territorial companies as part of national embargos and business activity restrictions aimed at certain citizens working for companies headquartered abroad as expatriates should be abolished.

➢ RULES OF ORIGIN

Orgalime fully supports the objective of simplifying and modernising customs legislation and procedures in the EU and worldwide. We think that a set of coherent rules of origin should be introduced in FTA negotiations, which includes TTIP, and that there should not be difference in the rules of origin in respective trade negotiations. We therefore agree that in the TTIP negotiations there is a need to harmonise rules of origin (based on those of the EU) to avoid the costly bottlenecks at the US border for European companies. We support simplified and rational rules of origin that are easy for customs administrations to verify.

➢ FACILITATION OF TRANSATLANTIC MOBILITY

As part of the acquisition of foreign products (machinery, components, etc.) by US customers and the assembly or installation in the US of "systems" purchased abroad, assembly or installation, commissioning and repair and servicing work are generally agreed upon. There is a lack of transparency over the extent to which foreign specialists can perform these tasks themselves within the scope of US legal provisions on entry and employment ("hands on" vs. "supervision"). This also applies to arrangements where foreign parent or affiliated companies provide the service for a US subsidiary or affiliate or where the service is provided for other foreign contract partners of the US customer in the US.

The TTIP should therefore aim to ensure the facilitation of short-term entry for business purposes and temporary assignments in order to provide such after-sales service and perform repairs, as well as assignments of intra-company transferees. In addition, TTIP could address enhanced transatlantic cooperation on the recognition of professional qualifications.

ANNEX – SPECIFIC CASES WHERE DIVERGING LEGISLATION LEADS TO ADDITIONAL COSTS FOR COMPANIES & SUGGESTIONS ON POSSIBLE SOLUTIONS

Note:

* *For this Annex some main areas of the electrical and the mechanical engineering industry are considered.*
* *The technical examples listed in the Annex form a non-exclusive list.*
* *Supplementary information on certain areas may be added later on.*

Mechanical Safety

Introduction

The example of the mechanical safety of machinery shows that regulations, which have come about mainly through consensus-based standards (ISO), offer a framework for an alignment of the prevailing framework conditions in the US and in the EU. These standards could be used on both sides of the Atlantic in support to legislation, should it be streamlined into common regulatory objectives through the identification of mutually agreed upon requirements and standards (such as those developed by the UNECE) that meet those requirements. Such important standards for mechanical engineering are:

- Requirements for risk assessment and risk reduction of machines/requirements concerning their sale - ISO 12100 (health and safety requirements and risk assessment) contains such principle technical requirements and requirements for risk assessment and risk reduction as part of the conformity assessment procedure of machines. Since ISO 12100 has also been implemented as an ANSI standard, there is broad consensus about these requirements on the safety of machinery. The American side thus has a basis for supporting legal requirements for machine safety based on ISO 12100 and the relevant ANSI standard.
- Safety distances - ISO 13857 contains requirements for safety distances to prevent hazard zones being reached by the upper and lower limbs. These requirements are important for all types of machines. If this has not yet been implemented as an ANSI standard, there could be a national implementation as part of the proposed alignment of technical requirements.
- Controls - ISO 13849-1 includes requirements for safety-related parts of control systems, which are of crucial importance for the application of principles of functional safety. ISO 13849-1 is a standard recognised worldwide in professional circles, which is regarded as state-of-the-art in many areas of mechanical engineering. We therefore propose that the ISO standard should be incorporated into ANSI standards.
- Permanent means of access to plant and machinery - For the safety of operators, means of access to plant and machinery are of crucial importance. In particular, measures to maintain the value and the availability of such safe accesses are essential. ISO 14122 contains requirements for accesses of the most diverse type and nature. We therefore propose that the ISO standard should be incorporated into ANSI standards.

Regulatory basis in the EU

The essential basis in the EU for the safety of machinery is the EU Machinery Directive (Directive 2006/42/EC.

Electrical safety

Introduction

Particularly in the area of electrical equipment, fundamental and conceptual differences in technical requirements can be observed.

Regulatory basis in the EU

In the EU, establishment of whether a product satisfies the essential requirements and may therefore be placed on the market and in service is governed for the area of electrical engineering almost exclusively by harmonised European provisions.

The general requirements for electrical safety of machines are governed in the EU by the Machinery Directive 2006/42/EC and for other electrical products by the Low Voltage Directive 2006/95/EC.

In the majority of cases, this essentially means that assessment is performed solely under the manufacturer's responsibility and that he applies the requirements for the affixing of the CE marking himself. Only in certain special areas (such as explosion protection, medical devices etc) is the involvement of an independent certification body also a requirement. Under this system, the application of certain technical standards provides manufacturer with a presumption of conformity with legislation. Application of the standards is however not mandatory.

Regulatory basis in the US

In the US, often there are no regulations governing placing on the market ("anything can be sold") of electrical and electronic products for use in trade and industry. Instead, regulation relies for the most part solely on the provisions governing occupational safety and health, safety of buildings and the operator ("not everything may however be used").

Specific technical requirements concerning the product's design and associated test methods are almost without exception specified in standards drawn up by the private sector. Despite having essentially the same objectives, the standards in the US and Europe governing one and the same product generally deviate strongly from each other. Only a small proportion of these deviations are attributable to the differences in power supply systems (230 V/50 Hz vs. 115 V/60 Hz), which must in principle be regarded as unchangeable. The greater part of the differences is due solely to the separate development of the standards over the years, and could be eliminated.

Products must bear the test mark of an NRTL in order to be put into service at workplaces. Similar requirements apply to products used in domestic electrical systems. The NRTLs conduct testing and certification solely in accordance with national US standards (generally UL or ANSI) that for the most part they choose at their own discretion or the use of which is binding under legislation, in particular the *National Electrical Code* for the area of electrical systems.

In practice, this often means that as far as possible, certified electrical components should be used within the control cabinet which is often included as an important component of the equipment supplied by the

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- UL 2011 (Factory Automation Equipment) - The standard concerns production equipment which is intended for specific applications in manufacturing, such as assembly of components, packaging, sorting, or counting of parts or processes, such as punching or cutting.
- UL 1740 (Robots and Robotic Equipment) - The standard sets out the requirements for robots and robotic equipment up to max. 600 V electrical nominal voltage in accordance with the National Electrical Code of ANSI/NFPA 70.

Situation of European Manufacturers

European manufacturers often must take note of the US standards that differ from European and international standards. However, finding the correct US code and the correct standards for the specific application often presents problems. This is caused by both the independent local US legislators (or "Authorities Having Jurisdiction" AHJ) and competing standards. Moreover, States' and local variations in legislation and standards cause confusion and costs for EU manufacturers interested in accessing the US market. For example, various States quote different editions of the NEC (National Electrical Code; NFPA 70) as being the applicable version (e.g. State 1 quotes the NEC 2011 edition, State 2 quotes the 2014 version).

The industry wishing to access the US market faces a system in which the observance of product requirements is standardised at national level. In case of mandatory certification test results from European test institutes (where available) are on the whole not recognised by their American counterparts. The CB procedure of the IEC, which is in place and functioning at international level in great parts of the world and serves the purpose of mutual recognition of test results by certification bodies, can be applied only in exceptional cases for exports to the USA due to the differences in the standards.

Possible solutions

Once again we consider that the revision of the legally binding essential requirements for electrical safety is not necessary at this point. The main differences are to be found in the more detailed technical specifications of standards used in support to this legislation.

Orgalime suggests the use of the existing IEC standards by US authorities in support to legislation. For example in the field of machinery, priority should be given to such an approach with regard to harmonising NFPA 79 NFPA 70 and UL 508A on the one side and similar IEC standards on the other side would remove a great part of existing technical barriers to trade.

For successful implementation it is essential that legislation on local or state level is covered by an agreement as well as on federal level.

Alternatively, the EU and the US should engage in concrete discussions of comparing the relevant US standards regarding relevant safety requirements in comparison to the IEC counterparts used in Europe and subsequently search for ways to harmonise the existing significant differences. This harmonisation activity should however not be conducted bilaterally, but at the level of the international standards organisations, since the harmonisation that has already been achieved with other regions of the world would otherwise be in jeopardy.

Consequently, the only technical code/standard that is allowed in these states is the aforementioned ASME code, a standard that describes the technical details of the product in similar detail as European product standards (but with considerable differences in the technical content).
In some US states the ASME certificate is not required by law or only for a very limited number of products (e.g. boilers only). In these cases it is, however, often the customer who requires compliance with the ASME code (and consequently also the ASME certificate since this is embedded in the standard itself). These requests are often due to requirements from insurance companies that are in charge of the in-service inspections (thus strictly speaking not required by federal or state law, but rather by the agency who supervises the customer). In contrast to vessels, piping is not required by law to conform to the ASME code although it is often required by the customer due to "practical" requests coming from in-service life. An ASME stamp for piping is typically not required.

In those cases where the ASME code is specified, be it by law or by the customer, the manufacturer has to strictly follow its specifications. Elements from other standards (e.g. European pressure equipment standards, "older" national standards) are normally not usable due the completely different technical approaches used in the ASME system. In practice this means that manufacturers of pressure equipment (US or non-US) when placing their products on the US market are in the vast majority of cases required to have an ASME stamp (certificate) and to build their products according to the ASME code.

Situation of European Manufacturers

The highly dominant role of ASME in the US means for worldwide-operating European manufacturers that they have to be familiar with at least two major standards: EN-standard for EU and ASME for North America. Given, however, that the ASME-code, like EN-standards, is very common also in many other parts of the world (e.g. Far and Middle East or petroleum industry), many European manufacturers know the ASME code and are ASME-stamp holders. They are used to following customer specifications, and building according to the American code does not per se pose a major problem.
The problems originating from the differences between ASME and the European code are rather in some technical details, e.g.: Quite often approvals for welding procedures or welders or for non-destructive testing (NDT) that are permissible in one system are incompatible with the other system. The European and the US system have two very different material approaches (chemical analysis, mechanical properties). Up to now the acceptance of a material from one standard system in the other system is often extremely difficult or requires enormous efforts.

Possible solutions

Keeping in mind that the inherent hazard potential of pressure equipment is rather high and that the existing legislations are to a large part based on experiences from the past, it appears to be quite unlikely that US or the EU would change or modify their existing legislation(s) to facilitate trade. Such a step would require enormous legal efforts and changes and could possibly cause considerable confusion due to the mixing of different safety approaches.

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Beyond the EU, Directive 94/9/EC is applied in other countries (Switzerland, Turkey or South Africa). A lot of customers in countries in the Far East require conformity declarations according 94/9/EC as well.

Regulatory basis in the US

There are requirements for electrical equipment in the US which are to be fulfilled by the manufacturer. Within the procedure of free trade in the US the process is accompanied by "Third Parties" who assess the alignment of the equipment with the requirements of certain standards. The acceptance procedure is not uniform all over the US, it slightly deviates from state to state.

The applied standards are majorly issued by NEMA (The Association of Electrical Equipment and Medical Imaging Manufacturers), or NFPA (American National Standards Institute/National Fire Protection Association) and their NEC (National Electric Code) often in conjunction with IEC Standards but specifically interpreted by the Nationally Recognized Testing Laboratories (NRTL).

Generally in the US, a certificate issued by a third party i.e. UL or FM (Factory Mutual) is requested by the user, where the individual procedures slightly deviate. For mechanical explosion protection there is no specific regulation in place.

Situation of European Manufacturers

European manufacturers have to seek for third party approval by an NRTL e.g. UL or FM. To get the certificate often only specific standards are accepted. This causes European manufacturers to fulfil different standards case by case and to design two different products, each for one market. The methodology of IEC and NEC 500 differ in the specific grouping of hazardous areas with the European system distinguishing three and the US system 2 areas. The area with the highest safety requirements in Europe (zone 0 corresponding to equipment category 1) has no NEC 500 equivalent. Also existing NEC 505 is pretty much in line (three identical categories each) with the IEC scheme but has a lower grade of application in the US. Hence both economic areas are not far away but hindered by traditional preferences.

Possible solutions

We suggest concentrating on the following steps:

Step 1 Make use of the IECEx-scheme in US and EU, since a lot of manufacturers already apply the IECEx scheme to serve the worldwide market. The IECEX scheme claims the application of certain IEC standards and a local third party certificate by a nominated IECEx-Certification Body.

The test report (ExTR) of the International Electrotechnical Commission System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres (IEC Ex scheme) is accepted in the US as well as in the EU as a conformity assessment procedure for equipment and services used in explosive atmospheres.

In both regions, the national standards for explosion safety are harmonised to the IEC standards with a few national deviations.

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