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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2. CONCRETE RECOMMENDATIONS

➢ CUSTOMS DUTIES AND TRADE FACILITATION

Orgalime strongly supports the elimination of customs duties in trade between the US and the EU. The tariffs for import of products of our industry from the US to the EU are at around 1.5% to 3% level on average, and the tariffs for export of EU engineering products to the US stand at around 2% to 4.5%. Even though tariffs are not the major obstacle to transatlantic trade for our industry, a full elimination of tariffs would result in direct savings of hundreds of millions of € for our industry.

The existing customs procedures and border enforcement cause high additional costs for companies on both sides of the Atlantic. Therefore, in the context of the Transatlantic Trade and Investment Partnership (TTIP) negotiations, the EU and US should work together to enhance electronic customs procedures and to cooperate towards implementing a system of standardised customs processes. This could include efficient seamless central customs clearance, taking into account the participation in international supply chain programs, the harmonisation of "pre-shipment" notifications and reporting requirements and the harmonisation of customs and security related standards. Required documentation and information obligations should be reduced to a reasonable minimum. There are already first positive signals regarding the mutual recognition of customs security programmes (C-TPAT[2]).

➢ COOPERATION ON REGULATORY ISSUES AND TECHNICAL BARRIERS TO TRADE

In a nutshell, the technical barriers to trade are twofold:

1) The first group consists of different technical standards between the EU and the US, partially with a longstanding history.
2) The second and more critical one consists of the lack of mandatory recognition of test results by NRTLs, which forces foreign companies to undergo revolving certification processes with heavy cost burden.

The above barriers cannot be removed by "mutual recognition". Without prior harmonization of standards, which needs some time because it is done by independent organizations, mutual recognition would cause disadvantages for our industry. The remaining cost intensive bottleneck of repeated testing by NRTLs would still exist, whereas US suppliers could use CE marking in the EU without further testing/certification procedures.

Overall, Orgalime believes that tackling regulatory divergences between the EU and the US will benefit businesses of all sizes and increase transatlantic trade flows. Currently the lack of

[2] *The Customs-Trade Partnership Against Terrorism (C-TPAT) is a voluntary supply chain security program led by U.S. Customs and Border Protection (CBP)*

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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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The ideal ultimate situation would mean having fully transposed international standards that are applied globally, without regional or national deviations. Standards alignment along with cooperation on regulatory issues can achieve the overall goal of European business, which is global market access on the basis of 'one standard, one test, accepted everywhere'.

Recognition of test results

Where technical provisions are identical, the results of testing should be mutually recognised. Where third party involvement is required in the electrical sector the IEC CB Scheme[3], based upon IEC standards, has been established internationally and should be used. In our view, the US administration should establish a "NRTL mutual recognition system" which would provide for the full and mandatory mutual recognition of test reports between the NRTLs within the US, similar to the European accreditation system set in place within the EU under Regulation 765/2008. This would avoid de-facto monopolistic behaviours from US certification providers.

Issues of transparency

Effective transparency in the field of standards supporting compliance with public policies is crucial.

In the EU the development of formal standards supporting compliance with legislation has always been an open process where all interested parties can participate through their relevant national standardisation body. American companies with an office in the EU could (and are already doing so) influence the development of European standards either indirectly, by participating in the work of National Standards Bodies (NSB) members of CEN, CENELEC or ETSI, or directly by participating in the work of a technical Committee under the mandate of a European trade association that has a partnership agreement with the European Standards Organisations (ESOs).

The European Commission publishes its standardisation work programmes and notifies stakeholders of its draft standardisation requests to ESOs. This enhances transparency of the process because it enables stakeholders to anticipate standardisation work, to get a facilitated access to the internal market and make knowledgeable decisions about becoming active in the European standard setting process.

However, in the US the decentralised nature of the whole system makes it difficult for European companies, in particular SMEs, to participate in the development of standards. In practice this means that European companies would need to spend much more time and efforts to continually

[3] The IEC CB Scheme is a multilateral agreement to allow international certification of electrical and electronic products so that a single certification allows worldwide market access

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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.

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➢ PUBLIC PROCUREMENT

Public procurement in the USA should be liberalised on all levels, including at state and local level. Regulations governing local content, "buy national" clauses and other restrictions (depressed areas and minority clauses, where still in force) should be withdrawn for suppliers from the EU member states. The EU's negotiators must obtain firm clarification of the degree to which any concessions by the US administration in Washington D.C. regarding public procurement will automatically apply in the 50 individual states, and how existing regional exemption provisions, where they apply, can be rescinded for companies in EU member states with the aid of the agreement. In any case , federal procurement procedures, including those bids co-funded by the federal budget, should give equal rights to contractors and suppliers from the EU.

We therefore call for a real opening of US public markets, not only at the federal level (with a removal of provisions that put American companies at advantage – for example the Buy American Act) but also at the States' level, especially since thirteen US States still do not apply the WTO Agreement on Public Procurement[4].

➢ DUAL USE ITEMS AND EXPORT CONTROL

In the framework of the transatlantic negotiations we should also achieve a removal of the extraterritorial application of the US regulations on the export of dual-use goods (EAR). A solution could be to recognise the export controls of these products in order to avoid duplication of costly formalities.

National laws and regulations with extra-territorial effect not only violate international law, as they disregard the political sovereignty of other states, but they are also a huge obstacle to global economic cooperation. Anyone who assumes the ultimately incalculable risk of trade restrictions that apply extra-territorially through the installation of foreign components into machinery will inevitably consider switching to "unencumbered" suppliers. There are cases where companies have restricted supplies from the US to an absolute minimum to avoid the extra-territorial US export controls as far as possible.

The TTIP should therefore ensure that no export restrictions with direct and indirect extraterritorial effect can be issued and that existing regulations with extra-territorial effect are rescinded. This applies both to trade and economic sanctions as well as to regular export control provisions for capital goods (dual-use export controls). Extra-territorial-oriented re-export restrictions (both in

[4] Those States include: Alabama, Alaska, Georgia, Indiana, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, South Carolina, Virginia and West Virginia

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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.

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3. CONCLUSIONS

The European engineering industry accords very high priority to the TTIP, with its objective of formulating a comprehensive, exemplary transatlantic agreement for the liberalisation of trade in products and services. The reality within large companies and now also many medium-sized companies is already shaped by their locations on both sides of the Atlantic: in other words, from the companies' perspective, progress in liberalisation pays off two-fold if both sides benefit from the agreement.

The US is currently one of the world's largest markets for our industry, and our companies hope that the overcoming of tariff and non-tariff barriers to trade will yield tangible cost benefits.
For the European engineering industry, represented by Orgalime, standardisation and conformity assessment barriers exist. Therefore, we support the transatlantic negotiations as a way to improve the technical cooperation by minimising as far as possible the existing differences in the respective regulations and minimising the number of competitive standards for the same product.

Orgalime also emphasises the need to maintain the support of ISO and IEC as preferred platforms to ensure compatible standards not only between the EU and US but also with third countries. We believe that the use of or, at least, alignment with international standards from ISO, IEC and ITU, is the way to go forward for the removal of technical barriers to trade between the EU and US.
In the framework of the transatlantic negotiations it will be crucial to achieve a real opening of the US public markets at both federal and state levels, a removal of the extraterritorial application of the US regulations on the export of dual-use goods (EAR), as well as mutual recognition of testing results where the technical provisions are identical.

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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.

Regulatory basis in the US

Regulations for machine safety can be found in US federal regulations and US State regulations. In addition, the OSHA (Occupational Health and Safety Organization) sets standards which contain provisions on occupational safety and machine safety. Monitoring of compliance is usually carried out by OSHA compliance safety and health officers. The US states have various occupational safety and health (OSH) programs.

In the field of standardisation, the American National Standards Institute (ANSI) participates in international standardisation (ISO) and draws up consensus-based standards with experts from various fields. In principle, such international ISO standards can be adopted as national standards.

In certain sectors (e.g. in robotics), ISO standards implemented by ANSI at national level do exist. However, in the field of cross-sector rules for the mechanical safety of machinery, ANSI is so far reluctant to use them with the exception of ISO 12100 (see above).

Situation of European Manufacturers

European manufacturers primarily have to research the State regulations to access the US market. Moreover, for most sectors CEN or ISO standards for mechanical safety of machinery do not formally apply because they have not been adopted by ANSI. Therefore, European manufacturers cannot prove the conformity of their machinery with the US requirements through the use of ISO standards. Consequently, they are obliged to provide the authorities with the technical file that would allow them to conduct risk assessment.

Nevertheless, in discussions with US OSHA officers, it often turns out that the substantive content of ISO and CEN standards for machinery is recognised as fulfilling the legislation's objectives.

Consequently, the whole procedure of repeating the manufacturer's risk assessment could be minimised if the US authorities at federal and state levels would accept CEN or ISO standards.

Possible solutions

Since there are different legal systems in the US and in the EU concerning the safety of machinery, it is difficult to revise the regulatory acquis for placing products on the market in the framework of a trade agreement.

However, negotiators and authorities should face TTIP as an opportunity in which both sides 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.

Moreover, the structured dialogue among manufacturers in international standardisation organisations and in particular in ISO can be beneficial. This can lead to a higher level of implementation of ISO standards on both sides of the Atlantic.

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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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machinery manufacturer and the control cabinet as a whole should have a certificate from an NRTL. This certification of machinery components is not legally mandatory but in fact a necessary prerequisite for the obligatory certification of the machine to avoid extensive and time-consuming separate testing of many components within the machine.

As NRTLs certifying a complete machine in most cases refuse to accept or make acceptance of a component of another NRTL costly, the component manufacturer is forced to use a certain NRTL without real choice or has to live with multiple certifications when supplying the same product to several customers.

Although already certified by an NRTL it can happen that an Authority Having Jurisdiction (AHJ) locally refuses to accept putting into service of the machine in the US.

Specific, legally binding technical product requirements exist in the US for certain consumer products. For the most part, consumer products are subject to certification requirements that are widely applied but nevertheless governed purely by private agreements; these are to a considerable degree a product of the strict US liability legislation. Even though no statutory obligation exists, it can be assumed that without such certification, products are virtually unmarketable. In this case too, certification is based upon US standards, primarily those of UL, and is generally performed by the same test institutes as those acting as NRTLs within the area of trade and industry.

Another area where progress could be made is laser products. Currently, all laser products (class I to IV) and products incorporating lasers which cannot be treated as removable laser, imported to the US have to be registered at the FDA regardless the application. Compared with existing practice in the EU it is unclear, why in the US lasers have to undergo such a special treatment. This additional registration is an additional effort that does not seem to be justified (at least, not for all classes or all products).

* * *

An overview of the most important US standards:

- NFPA 79 (Electrical Standard for Industrial Machinery), the latest version was produced in 2012. The basic structure and content of NFPA 79 is largely identical to the current international generic standard IEC 60204-1:2005 (Safety of machinery – Electrical equipment of machinery). However, there are numerous formal and technical differences between these two standards in relation to substantive details. Some important differences: Wiring requirements, Wiring in the housing, single wire marking, 50% filling of the cable ducts, Bending radius of the cable, looping and fastening of excessively long cables, Cable cross-sections, Cable core colours, Cable laying, cable trays, conduits
- NFPA 70 (also published as “National Electrical Code” NEC), the latest version was produced in 2014. This is a manual for electrical installations inside buildings. This standard is made mandatory for electrical building installations by local or state law and local adaptions sometimes partly deviate from the original version.
- UL 508A (Industrial Control Panels) - This standard covers the making of the control cabinet. In terms of IEC documents, in this case the IEC 60439 series "Low voltage switchgear and control gear assemblies" can be regarded as the international equivalent.

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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.

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Pressure equipment

Introduction

Pressure equipment such as boilers and pressure vessels are, due to the enormous hazard potential of high pressure products, subject to quite elaborate safety regulations in most countries.

The term “pressure equipment” has a rather wide scope: It comprises large industrial equipment like steam boilers or hot water boilers in power plants, pressure vessels (like storage tanks, process vessels, distillation columns, reactors, steam crackers etc.) and industrial piping in the chemical industry, together with their safety accessories. Depending on national/regional legislations it can also encompass “smaller” types of equipment like pressure vessels or piping attached to machinery, pressure accessories with a special function (e.g. measuring devices) and even smaller appliances like steam cookers or fire extinguishers.

Due to the historic development of most pressure equipment legislations, the safety approaches and philosophies that are applied in different regions of the world vary considerably: While one frequently finds regulations that focus on the product quality and safety, there are also systems that are aimed at the manufacturing companies themselves and hence grant market access only to certified pressure equipment manufacturers who conform to a certain quality level. But also at the level of technical codes and standards, the differences are considerable (allowed materials, calculation approaches, tests required etc.). These differences are the main reason why little progress in this field has been made in standardisation processes for pressure equipment on the ISO-level.

Regulatory basis in the EU

Products that fall under the term “pressure equipment” are subject to one of two European Directives: Directive 2014/29/EU on simple pressure vessels. Products in its scope are mainly breaking cylinders for trains and trucks and storage vessels for compressed air applications. Directive 97/23/EC (PED = Pressure Equipment Directive) covers all other types of pressure equipment: boilers and pressure vessels, industrial piping, pressure accessories and safety accessories. Any pressure equipment that is placed on the EU market, whether made within the EU or imported from outside the EU, has to comply with the technical requirements that are laid down in the appropriate directive.

The American pressure vessel code ASME does not comply in all aspects with the European PED.

Regulatory basis in the US

Although there is one highly dominant technical approach for manufacturing pressure vessels to be placed on the market in the US (the ASME Code: ASME = American Society of Mechanical Engineers) one finds that the legal requirements vary quite sharply across the different US states. There is not one single country-wide law that would uniformly regulate the placing on the market of pressure equipment in the US, but every state (sometimes even single counties or cities) has its own regulation: Some US states have rather strict technical laws, some of them requiring that (both US- and non-US-) manufacturers of pressure vessels who want to place their products on the US market, can do so only having an ASME stamp, a license (with an extensive audit procedure) that certifies their ability and skills to manufacture according to the ASME system.

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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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An alignment (or a "mutual" 1:1-acceptance) of the legal systems for pressure hazards in the EU and in the US does therefore not appear to be a high priority objective. Nevertheless, there are issues on the working (i.e. standard) level that frequently cause irritations or unnecessary technical barriers and should be addressed during TTIP negotiations.

Therefore, we suggest negotiations on mutual recognition of certificates in the fields of welding or non-destructive testing. It would be of considerable help for European manufacturers if the results from standardisation activities on welding or NDT on the ISO-level would finally be implemented (and acknowledged) in the existing product standards in ASME. Since the US play an active role in the ISO-TCs on NDT and welding it would be highly desirable that the respective ISO-standards are then also accepted within the American pressure equipment code.

Some years ago talks were initiated between EU-representatives and ASTM-experts (ASTM = American Society for Testing and Materials – the material system on which ASME is based). The goal was to find possibilities to facilitate an easier mutual acceptance of materials (steel grades) for pressure equipment as far as this is technically feasible. The talks were unfortunately stopped after very few meetings. Although the discussions are certainly very technical and difficult – one should try to resume these talks.

Explosion protection

Introduction

The field of explosion protection can be subdivided into two different areas, namely mechanical explosion protection and electrical explosion protection. While in the field of electrical explosion protection there is a considerable degree of similarity between the American and the European approach, one presently finds large differences in the interpretation for mechanical hazards.

Whereas in the EU there are elaborate mandatory requirements for mechanical equipment, there is no such counterpart in the US. The alignment of the scope for explosion protection (i.e. electrical and mechanical) in both economic areas is a main issue. United Nations Economic Commission for Europe (UNECE) is working on such a worldwide regulation within their task of limiting the "friction losses" to increase the economy.

Regulatory basis in the EU

The Directive 94/9/EC (revised by NLF as 2014/34/EU) sets the essential requirements for mechanical equipment used in potentially explosive atmospheres. The scope of the Directive covers both electrical and mechanical equipment with respect to their ignition properties. It also covers combined machinery and forces the manufacturer to analyse and assess interfaces and interaction of machinery parts. The directive is supported by specific harmonised standards which refer to specific matters. All equipment intended to be placed on the EU market has to fulfil the requirements. The conformity with the essential requirements of the directive requires in most cases a third party test performed by a so-called Notified Body in the EU.

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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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Nevertheless both, US and the EU request a national resp. regional certificate, causing additional costs and time for the manufacturer. This could be streamlined by accepting also the full IECEx certificate under the Directive for equipment and protective systems for potentially explosive atmosphere (ATEX Directive 94/9/EC) in the EU as well as under the NEC Article 500 in the US in a mutual agreement.

Step 2: A worldwide "ATEX Directive" implementing mechanical equipment. Since the EC Directive 94/9 is the only legislation worldwide including mechanical explosion protection and made a great contribution to product safety, the directive can be taken to establish a common legal ground for such equipment. This opinion is supported by a lot of countries outside the European Union which use such certificates too. An appropriate path towards this solution may be the work of UNECE on the matter.
An additional approach may be to "copy" the IECEx scheme for mechanical equipment and go for mutual acceptance of third party certificates on the basis of ISO/IEC Standards.

Note: there are many other technical examples, for example regarding regulations in the field of food contact materials, where Orgalime can provide further input and suggestions for possible solutions.

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