ORGALIME

Comments

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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.

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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.

Ø 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.

Ø 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

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Ø Surveillance visits:

For a product approved by a NTRLs, a system of 4 quality surveillance visits a year is imposed on a company. When a company has products approved by different NTRLs, 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.

Ø 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.

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Ø 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.

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