

## Orgalime priorities for the upcoming EU-US trade and economic negotiations

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### 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. Transatlantic relationship has an unexploited potential and Orgalime strongly supports increased cooperation between the EU and the US.

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. Issues that should be tackled by the upcoming negotiations

Orgalime expects from future trade and economic negotiations following outcomes:

- Elimination of all tariffs
- Elimination of double formalities on export controls of dual-use items
- Simplifying and speeding up of the CPSC notification procedure in case of a potential safety issue (the current procedure is very time consuming and, without legal support from specialised counsel, it is not possible to manage without risking huge fines and massive recalls in the US market)
- Conclusion of mutual agreements to accept each other's certificates (for example when exporting medical equipment to the US, the main issue is compliance with all the FDA regulations. It would be a big step forward, if there would be mutual recognition agreement)

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*Orgalime, the European Engineering Industries Association, speaks for 37 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 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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- There is a trend in the US that logos (coming from IEC, CE, WEEE) are not accepted in the US without additional written explanation: this inevitably leads to special US-only packaging requirements – creating additional costs for manufacturer.

### **3. Orgalime concerns and suggestions regarding specific non-tariff barriers on the US certification market**

In the area of electro-technical equipment, different US governmental bodies, notably OSHA (Occupational Safety and Health Administration), have created a framework which makes it very burdensome and costly for EU companies to act on the US market. Companies suffer from a malfunctioning of the US certification market, which has its cause in how OSHA deals with accredited National Recognized Test Laboratories (NRTLs) that have the power to determine that specific products meet consensus-based standards of safety.

European component manufacturers have been suffering for years the consequences arising from the practices the market leader in the US certification market. Taking advantage of the non-competitive character of the US certification market, the market leader is effectively in a position to exploit his position and reinforce it, thereby leading to an increasing hold over the certification market for certain categories of goods. Most NRTLs accept certificates issued by other NRTLs with one notable exception: the market leader, UL, which due to historical reasons occupies much more than 50% of the market (the overall 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. 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. Therefore many engineering companies feel that the behaviour of UL constitutes an abuse of their dominant position.

#### **Acceptance of certificates:**

- All NRTLs should, in the absence of 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 it is the case in Europe with accredited laboratories and certifiers.
- The US certification system should undergo a reform not only on paper but also in practice. In particular, OSHA rules for accreditation of NRTLs should clarify that an NRTL in charge of testing a final product cannot be held liable for the failure of the final product caused by the failure of a component certified by another NRTL but otherwise well assembled.

## **Standards and price differences:**

- NRTLs should not set their own standards or own 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 given that 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 than CSA have been observed).

*Examples of price differences:*

- *Price difference for annual fee between UL vs NTRL x : factor of 2 to 2,5*
- *Price difference for audit cost between UL and NTRL x : factor of 3*
- *Audits conducted by other certification bodies, but ordered by UL: need to be paid twice (once original certification body + once to UL)*
- *Administrative updates: cost: factor of 2*
- *Production inspection (quarterly follow up visits): UL handles a “file system” in which different equipment (tested for the same safety standard) is classified in another file. Costs are not related to the visit itself (time spent), but to the fact that different files they have checked. Suppose that production is ready for 3 different products, each classified in a different file: this leads to 3 times the cost, whereas NTRL x only charges once (the visit, not the products).*
- *As an example 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. A company had proposed a strategy on basis of risk management by means of a template for all devices, as the risk assessment is similar for all devices. As a result the company wished to arrive at a price range equal to the cost of an earlier upgrade to the 2nd edition. This was not accepted by UL and the company will have to pay individually for each device almost 1,5 times the price for third party certification compared to the previous 2<sup>nd</sup> edition.*
  
- 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 these “Americanised” IEC standards, UL uses a lot of own UL standards for certification which are different from IEC and/or other national standards (as ANSI/ISA, FM, IPC etc.).
- Our recommendation for the US is to establish a system similar to the European directives with listed harmonized ANSI standards as a common basis for the conformity assessment by a NRTL. This would lead to more transparency and expedite the comparability and interchangeability of conformity assessments between different NRTLs. Testing performed by one NRTL

would be accepted by all other NRTLs when appropriately combined with products which might have been tested and certified by a second NRTL.

- Furthermore, 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.

#### **Surveillance visits:**

- Surveillance visits: for a product approved by any of the NRTLs, a system of four quality surveillance visits a year is imposed on a company. When a company has products approved by different NRTLs, it undergoes four visits from each of them, which increases the budget and length of the procedure.
- Our recommendation is to establish a quality inspection programme performed by only one NRTL and accepted by all other NRTLs. This would be similar to the application of quality systems for equipment manufacturers under the ATEX directive (ISO/IEC 80079-34).

#### **Other requests:**

- Quality Assessment Reports should be accepted for market entry into US
- Certificates of Conformity (CoC) and test reports should be accepted for products delivered to the USA and Canada too
- The US should, like the EU, Japan and others, recognise IEC standards, particularly when the US National Committee has voted in favour of the standards and moreover when those standards have taken on board as U.S. practices.
- The US should enter into the worldwide system for conformity, testing and certification of electro-technical equipment and components (the FCS of IECEE – the full certification scheme of IECEE).

#### **Recommended elements for a future political and economic agreement**

- We request further technical harmonisation (IEC/ISO) and more open-minded regulation on third party inspection bodies and laboratory involvement.
- The US could apply the bottom-up approach as it has a strong UL NRTL network already in place, through an improved top-down monitoring-guidance of those third party organisations. The US should have in mind the need to expand the possibilities of global technical barrier free trade (GTBFT), in other words through entering into the worldwide system for conformity, testing and certification.

#### 4. Conclusions

Although the EU and the US have a long standing tradition of cooperation, we feel that in the electro-technical area 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.