

Position Paper

Brussels, 15 March 2016

Regulatory Cooperation in the Transatlantic Trade and Investment Partnership

EXECUTIVE SUMMARY

Orgalime calls for progress on the Transatlantic Trade and Investment Partnership (TTIP) negotiations. The TTIP is a key priority for the European engineering industry, with its objective of formulating a comprehensive, exemplary transatlantic agreement for the liberalisation of trade in products and services. The USA is currently one of the world's larger markets for our industry, and our companies hope that overcoming both tariff and non-tariff barriers to trade will bring about tangible cost benefits.

Additionally, standardisation and conformity assessment procedures should facilitate transatlantic trade, not become technical barriers for both the European and the American engineering industries. Therefore, we support the transatlantic negotiations as a way to improve the technical cooperation by reducing as far as possible the existing differences in the respective regulations. We believe that the alignment with international standards from ISO, IEC and ITU, is the way forward for the removal of technical barriers to trade between the EU and the USA.

Overall, Orgalime believes that tackling regulatory divergences between the EU and the USA will benefit businesses of all sizes and increase transatlantic trade flows. Currently, the lack of regulatory convergence obliges companies to invest time in diverging procedures to prove compliance. This constitutes an extra cost and a barrier to trade for companies, impacting especially the small and medium-sized ones.

Two important types of technical barriers to trade between the EU and the USA are:

- Different technical standards between the EU and the USA and how they are used to show compliance with legislative requirements.
- Lack of mandatory recognition of test results by (US) Nationally Recognised Testing Laboratories (NRTLs), which forces companies to repeatedly undergo certification processes entailing high costs.

These barriers cannot be removed by the "mutual recognition" of standards. Without prior EU-US harmonisation of the essential regulatory requirements, which would need time, the mutual recognition of technical standards would be disadvantageous for the European industry. In this

Orgalime, the European Engineering Industries Association, speaks for 42 trade federations representing the mechanical, electrical, electronic, metalworking & metal articles industries of 24 European countries. The industry employs some 10.3 million people in the EU and in 2014 accounted for more than €1,800 billion of annual output. The industry accounts for over a quarter of manufacturing output and a third of the manufactured exports of the European Union.

scenario, the bottleneck of repeated testing by NRTLs would still remain in place for European manufacturers exporting to the USA, whereas US suppliers could use the CE marking to place their products anywhere in the EU without further testing/certification procedures.

Regulator-to-regulator cooperation

Orgalime welcomes the Commission's proposal that TTIP should establish transatlantic cooperation mechanisms among all the relevant regulators¹. This should also include EU Member States and US States, whenever they can influence the requirements for placing products on the markets where they have jurisdiction, either for consumer or professional use.

Any future regulatory steps should support the European Directives that are currently being or have been recast/aligned with the New Legislative Framework. The latter provides clarity and predictability to manufacturers when a product-specific Directive is revised, because the regulator is obliged to choose among a common set of conformity assessment procedures and definitions that are laid down in these pieces of legislation.

Moreover, we fully support the commitment to closely cooperate in the development of international disciplines. The application of international instruments to which both partners abide, for example agreements under the United Nations Economic Commission for Europe (UNECE), could be a suitable way to harmonise legislation or assess regulatory equivalence between the two trading partners.

Orgalime welcomes the planned Regulatory Cooperation Body in TTIP; this will entail creating a 'living agreement' so as to facilitate moving towards achieving regulatory coherence and gradually producing solutions acceptable for both sides.

Standards

The EU and the US have different standardisation systems, which have been shaped over many decades, reflecting each party's history, culture and values. However, there are global standardisation bodies recognised by both parties that could form the foundation for future cooperation towards common standards. We consider that any steps in regulatory cooperation should be accompanied by a corresponding cooperation at standardisation level. Orgalime firmly supports the principle that TTIP should promote standardisation work primarily at ISO, IEC and ITU level, at least for the standards that are relevant for both constituencies. 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'.

Transparency in setting standards

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. All interested parties, including US companies, can participate through their national standardisation bodies, which are members of CEN, CENELEC or ETSI. Thereby, US companies present on the European market can influence the development of European standards, which will grant them access to the EU single market. Information on standards and future

¹ EU's proposal on regulatory cooperation (February 2015) http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc 153120.pdf

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standardisation requests, interacting with legislation are displayed online by the European Commission, and all standards listed are available for purchase from the national standardisation bodies. US companies therefore have the same rights in this area as do the European companies.

On the contrary, the decentralised nature of the US system makes it difficult for European companies, in particular small and medium size businesses, to participate in the development of standards with a US-wide outreach. In practice, such fragmentation and lack of transparency means that European companies need to spend much more time and effort to continually monitor new standardisation work items initiated by the US Standard Developing Organisations (SDOs). This also results in the need to purchase standards from different sources, which is becoming increasingly complex and costly.

Detailing how US federal and sub-federal legislation interacts with standards, including notifications of scheduled changes and listing of standards that specify the applicable conformity assessment procedure, would increase the transparency and predictability of the US standardisation and conformity assessment system. This could be done within the existing legal and regulatory framework and would benefit both European and US businesses.

In the short term, we suggest that the USA establishes a single portal, listing in a transparent way the applicable legislation and any linked standard, the accredited SDOs under the ruling of US Federal agencies (OSHA, FCC, etc....), their relation to applicable Federal or State legislation per industrial sector, where to apply for active participation in the standardisation work, and where to buy the available standards.

In the longer term, US and EU regulators should commit that only standards developed in close cooperation with IEC and ISO should be used for supporting compliance with both EU and US legislation.

Mutual recognition of conformity assessment procedures

Currently, direct mutual recognition of conformity assessments procedures cannot be effectively implemented without significant disadvantages for our industries, due to completely different regulatory philosophies and competences in the EU and the USA.

Orgalime industries value the European system whereby EU authorities rely on the manufacturers' declaration of conformity (DoC) for a wide range of products and require third party conformity assessment certificates only for a limited number of product groups, such as dangerous machinery. Therefore, we call on negotiators to preserve the flexibility of accessing the European market in the process of streamlining the EU and US regulatory systems. This presents an equivalent advantage for both EU and non-EU business.

Recognition of test results among Nationally Recognised Testing Laboratories (NRTLs)

Where technical provisions are identical, the results of testing should be mutually recognised and accepted among NRTLs. Where third party involvement is required in the electrical sector, the IEC CB Scheme, which has been established internationally based upon IEC standards, 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 NRTLs in the USA,

similar to the European accreditation system set in place within the EU under Regulation EU 765/2008. This would mitigate *de facto* monopolistic behaviour from some US certification providers.

Cooperation at enforcement/market surveillance level

Orgalime supports the official EU position² to reinforce the existing elements of cooperation between EU Member States' market surveillance authorities and US federal and sub-federal enforcement authorities. Moreover, we consider it necessary to involve customs authorities from both sides in this cooperation agreement, as they constitute the first filter for preventing non-compliant products from entering the EU and US markets in breach of their respective legislative framework.

Furthermore, we suggest that relevant EU and US authorities should establish a regular dialogue involving interested industry stakeholders on both current and future challenges, for instance traceability to the liable economic operator, e-labelling of products, or other demonstration of conformity procedures.

The present paper builds upon the past Orgalime positions, which can be accessed via www.orgalime.org ³

Responsible Advisers:

Željko Pazin, Philippe Portalier, Silvia Selandari, Caio Lobo

Email: first name.second name @orgalime.org

The European Engineering Industries Association

² EU position paper TTIP regulatory issues - engineering industries (January 2015) http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc 153022.pdf

³ - 21 April 2015 Orgalime comments on EU's position paper on the engineering industries and TTIP.

^{- 21} April 2015 Orgalime comments on the Commission's proposal for Regulatory Cooperation in the framework of the Transatlantic Trade and Investment Partnership (TTIP).

^{- 8} May 2014 The Transatlantic Trade and Investment Partnership negotiations - a way forward.

^{- 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.