



Conformity Assessment Perspective on TTIP

Together ACIL, CEOC, and IFIA represent the vast majority of testing, inspection, and certification service providers worldwide. Our members are located in both Europe and the United States, as well as in other geographies, and our collective memberships consist of both small and medium sized (SMEs) companies/laboratories and larger entities. Given our work with manufacturers, importers, and distributors to help them with the appropriate conformity procedures to place their products in the market, while ensuring product compliance, we are collectively committed to ensuring that the Transatlantic Trade and Investment Partnership (TTIP) sets a solid foundation to facilitate trade between Europe and the United States.

International trade is important for both Europe and the United States. As guarantors of growth, it secures prosperity and employment. However, the value creation chain is becoming ever more complex and safety cultures vary between different economic areas. Products that are sold in the European internal market, the United States, and worldwide must meet the relevant legal requirements and standards – in other words, they must be conformant.

With our competence, neutrality, and objectivity, the conformity assessment organizations of ACIL, CEOC, and IFIA ensure that manufacturers, trading partners, governmental bodies, and consumers can trust in the conformity of products. Third-party independent conformity assessment is an integral part of well-functioning trade. ACIL, CEOC, and IFIA and their members support the ambitions of the Transatlantic Trade and Investment Partnership (TTIP) and we would like to contribute our proposals. We would like to thank both the European Commission and the U.S. Government for consideration of our viewpoints.

Supporting Trade Between Europe and the United States

ACIL, CEOC, and IFIA agree that trade between Europe and the United States could be enhanced through **the reduction of Non-Tariff Barriers to Trade (NTBs)**. In working towards this goal, it is necessary to take into account well-established and practical differences in our product safety systems, including the expected role of government, and often differing requirements for products and services destined for the European and U.S. markets. These differences arise from material law, standards and standards development procedures, conformity assessment, regulatory, and market authorisation requirements that differ or are not mutually recognised.

NTBs – What Can Reasonably be Achieved

TTIP negotiators have declared their intention to tackle NTBs through harmonised or compatible standards and mutual recognition. While our associations agree that these are laudable goals, we believe that for a number of reasons that there will be extreme challenges to their application.

To achieve wide-ranging legal harmonisation between the two markets, a common institutional framework between Europe and the United States would be needed and efforts to amalgamate approaches to standards development and adoption would also be required. The Regulatory Cooperation Body proposed by the EU would, if accepted, allow exchanges between regulators, but it would not have the power to adopt legal acts. Governments on each side of the Atlantic would therefore at least have to agree to harmonisation measures for regulation and legislation in the relevant areas, and standards or procedures would have to be developed to address these

requirements. In the end, if the regulatory status quo is changed for individual product sectors, fundamental regulatory goals and suitable protective measures for citizens will be significantly impacted. Furthermore, given the limited role of the government in voluntary standards development and adoption, which make up the majority of standardization activities, regulatory alignment alone would be insufficient.

Against this backdrop, it is clear that wide-ranging and consistent harmonisation between Europe and the United States would inevitably reach its limits. There is insufficient compatibility between the legal systems and there is not a common institutional framework.

It is also attractive to highlight mutual recognition of product testing and conformity assessment results as a trade facilitating tool in TTIP. However, the principle of mutual recognition can also only be effective when products share common standards and the same, trusted mode of conformity assessment. It is necessary for those participating in the respective other market to have sufficient trust in the product-specific standards and applicable regulations and the resulting level of protection which apply in the product's point of sale. However, experience in Europe shows that products with a particularly high hazard potential for people and the environment cannot be marketed according to the principle of mutual recognition. Rather, harmonised legislation was created for such products, based on Directives and Regulations. For example, marketing of medical devices, motor vehicles, lifts, machinery, and toys is today uniformly regulated throughout the whole of Europe. In the United States, for example, workplace safety is uniformly regulated by Federal Regulations, but products which have been examined and listed against product specific standards by a Nationally Recognized Testing Laboratory (NRTL) may still be denied access to the market by the local authority having jurisdiction (AHJ) unless the AHJ is open to accepting the product by that NRTL.

Another complicating factor is the use of different forms of conformity assessment for some products in Europe, such as Supplier Declaration of Conformity (SDOC) versus reliance on third-party testing, follow-up inspection, and market surveillance by the conformity assessment body in the United States as a prerequisite for market access. Recent studies conducted by CEOC and IFIA comparing compliance between SDOC and third-party tested products in Europe demonstrated vulnerabilities with the SDOC system in Europe versus a strong level of superior compliance with requirements for third-party tested products¹. Against this backdrop, it is clear that wide-ranging and consistent application of the principle of mutual recognition of products under TTIP would also certainly reach its limits.

What TTIP Should Do

In order to achieve the stated aim of establishing a seamless trading market between Europe and the United States, we believe that TTIP should set trade-related guidelines that allow conformity assessment bodies to serve the needs of manufacturers who want to sell in both markets. **Transatlantic acceptance of conformity assessment results** (national treatment) based on the requirements of the target market is a preferred approach. Small and medium sized companies especially benefit from this approach as it opens the possibility of having the conformity of a product tested by an accredited body at the home location, against the requirements of the target market.

1. Easing market access with “Cross-Border Conformity Assessment Activities”

¹ http://www.ifia-federation.org/content/wp-content/uploads/Consumer_Product_Safety_Study_2014.pdf

Manufacturers must ensure that products placed on the market conform to relevant product-specific requirements. Manufacturers are liable for their products no matter which conformity assessment procedure regulators have foreseen. Regulators may require third-party testing as a necessary prerequisite for proof of conformity, for many reasons, including product safety, protection of health and the environment, and risk management.

Conformity testing of products for both sides of the Atlantic can be simplified, however, if conformity assessment bodies at the home location are also authorised to test products in accordance with the regulatory and technical (standard-based) requirements that apply in the other economic area. Facilitating cross border testing using this national treatment approach would enable one-stop shopping, reducing the number of conformity assessment bodies that a manufacturer may have to employ, enhancing the product's time to market. In cases where assessment of the conformity can be made based on identical requirements, there would then be the added benefit of no additional testing. This approach would also support limited additional testing only to address deviating national product requirements. Use of international conformity assessment systems such as the IEC conformity assessment schemes² is in some cases an efficient approach to reduce redundant testing.

2. Facilitating conformity assessment accreditation

Conformity assessment bodies (including first-party in-house laboratories and third-party testing/certification/inspection bodies) must reliably demonstrate their competence in all aspects of conformity assessment, including the testing and certification of the product, to the respective authorities while taking into consideration the legal and standards-based requirements. Accreditation of conformity assessment bodies provides confidence to manufacturers, consumers, retailers, and regulators in products that are brought to the market. While we **support strong accreditation requirements** as a benchmark to ensure competence, the costs associated with multiple local accreditation requirements as well as duplicative accreditation for conformity assessment bodies on both sides of the Atlantic can be additional burdens that impact transatlantic trade. Conformity assessment bodies with multiple locations are significantly impacted by this issue. We recommend that TTIP explore ways to streamline accreditation requirements in the European Union and United States, while still ensuring competence. To facilitate trade and ensure consumer protection, it is also essential for all testing laboratories and conformity assessment bodies to have equal competence. We therefore recommend that TTIP explore how to ensure that first party in-house laboratories are held to the same high competency requirements as third-party laboratories and consider the implementation of an accreditation scheme for testing and certification, based on appropriate ISO/IEC Conformity Assessment (CA) standards (i.e., 17025, 17065, 17011, and 17021). These can be applied to independent laboratories and conformity assessment bodies by the accreditation bodies to better ensure the parity of conformity assessment results.

3. Facilitating regulatory coherence and sectoral cooperation

ACIL, CEOC, and IFIA support TTIP's commitment to regulatory coherence, transparency, and additional efforts by select industry sectors to work towards standards, regulatory alignment, and data sharing. Any efforts that can promote greater transparency, stakeholder participation, and accountability in the development of regulations, helps testing and conformity assessment bodies function effectively and ultimately helps manufacturers. In addition, any steps that can be taken to reduce or eliminate unnecessary regulatory differences will reduce cost and speed products to the marketplace.

² <http://www.iec.ch/conformity/what/>

About ACIL, CEOC, IFIA

ACIL (the American Council of Independent Laboratories) is a 77-year old U.S.-based trade association representing a diverse group of third-party conformity assessment organizations operating globally. With 150 member companies representing 1,500 facilities globally, our members offer services in product testing and certification, environmental sciences, food sciences, construction materials, and engineering. Contact: Milton Bush, Chief Executive Officer, ACIL +1.202.887.5872; mbush@acil.org.

CEOC International is a European trade association, created in 1961, representing 29 members from 19 countries. Our members are active in over a hundred countries around the world — giving a truly international dimension to our organisation. CEOC International members are accredited by public authorities to provide inspection and other conformity assessment services for a wide variety of equipment such as pressure vessels, lifts, machines, cranes, medical equipment, electrical and heating installations, industrial plants, consumer products, and toys. Most of them are notified bodies within the framework of the EU New Approach Directives. Contact: Drewin Nieuwenhuis, Secretary General, CEOC International +32.2.511.50.65; drewin.nieuwenhuis@ceoc.com.

IFIA (the International Federation of Inspection Agencies) is a trade federation that represents over 50 of the world's leading international testing, inspection, and certification companies, including many well-known European and US members. These have a combined turnover of in excess of €21 billion and over 290,000 employees. IFIA members' activities encompass every aspect of inspection, certification, and related testing. All applicants for IFIA membership are required to implement the IFIA Compliance Code, and members' continuing compliance is independently audited on an annual basis. Contact: Roger Brockway, Director General, IFIA +44.0.1403.751764; roger.brockway@ifia-federation.org.