CONFORMITY ASSESSMENT PERSPECTIVE ON TTIP: COMMENTS ON PUBLICLY AVAILABLE TEXTS
SEPTEMBER 2016

SUMMARY

- **Support for TTIP**: IFIA supports negotiations that will result in a comprehensive, high-standard and market-opening trade agreement for the third party conformity assessment sector. The current proposals outlined in the publicly available TTIP negotiation texts present significant concerns for IFIA as the proposals do not meet the high-standards which are the stated objectives of both economies in negotiating such an agreement, especially as it relates to regulatory provisions.

- **Third-party is a viable conformity assessment method that brings value**: TTIP must preserve the flexibility and neutrality of conformity assessment methods allowing regulators and good regulatory processes to identify and select the appropriate methods of conformity. Reliance on third-party conformity assessment is a proven cost effective method for governments, manufacturers, retailers, trading partners and consumers.

- **EU and U.S. safety systems must be respected:** The EU and U.S. safety systems, including the expected role of governments and requirements for products and services vary due to historical, institutional and societal differences. To ensure that the level of protection to consumers' health, safety and the environment is not reduced or undermined, conformity assessment procedures must only be accepted by the other Party when they are deemed equivalent both in terms of procedure and in terms of the level of accreditation required of any (first or third-party) conformity assessment body.

- **Regulatory cooperation and harmonization of international standards can reduce cost and time to market:** Regulatory coherence and convergence that promote greater transparency, stakeholder participation, and accountability and the harmonization of international standards can reduce cost and time to market for manufacturers. Efforts should ensure that safety levels are maintained or improved.

- **Technical barriers to trade (TBT) should be addressed solely within the TBT chapter**: IFIA believes that inclusion of TBT-like provisions (including language on standards, inspections, market-surveillance, and equivalence) beyond the TBT chapter that are weaker than the overarching TBT obligations sought, undermines the strength of the TBT chapter as a whole. Any provisions on technical regulations, standards, and conformity assessment-related matters, should be included solely within the TBT chapter which governs such matters. Doing so will provide the most clear and comprehensible framework for addressing regulatory considerations.

- **TTIP should reduce duplicative regulatory burdens through national treatment:** Easing market access with "Cross-Border Conformity Assessment Activities" by relying on national treatment will reduce cost and time to market for manufacturers.

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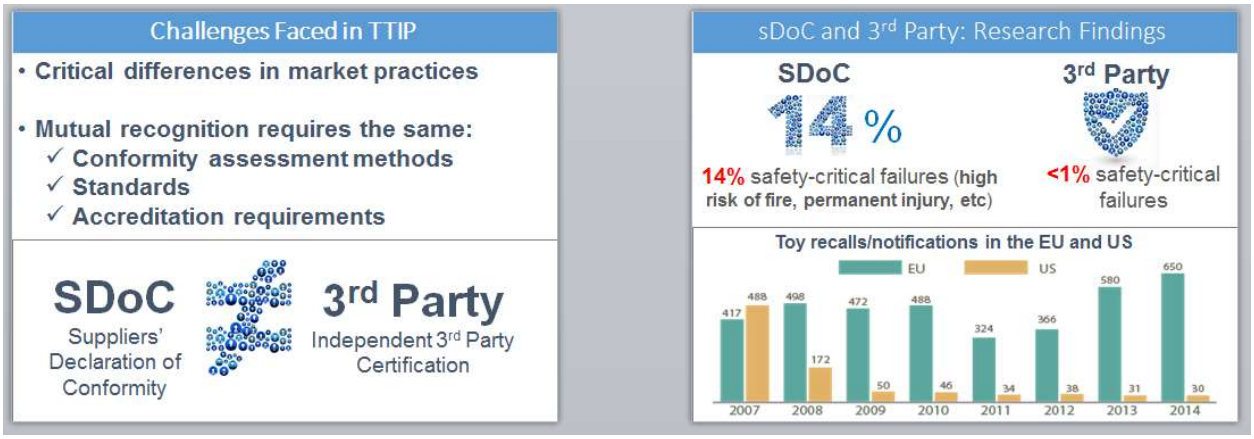
INTRODUCTION

IFIA is the global trade association representing independent third-party conformity assessment bodies (CABs) that provide testing, inspection, and certification services across a wide range of sectors: medical devices, food, consumer products, industrial plants, power lines, pipelines, petroleum and agriculture among others. IFIA's members are present in more than 160 countries and employ more than 500,000 across the globe, the majority of whom are highly trained sector-specific technical experts.

Third-party conformity assessment provides greater assurance that products have been correctly manufactured, tested, inspected and certified during the production process and that controls are in place to ensure safety in all stages of global and diverse supply chains. IFIA's members provide innovative and cost effective solutions to help manufacturers improve the quality, performance and safety of their products. Services include: safety evaluation of sourcing materials, definition of test protocols, supplier validation, factory audits, raw materials checks, testing from the design to final production phases, inspections, container loading supervision, market surveillance, correction plans, social auditing, among others.

Independent third-party conformity assessment has been shown to reduce the number of non-compliant products in the market. Data from numerous sources including ProSafe, TUKES, IFIA, RAPEX all suggest significant differences in levels of compliance in geographies with supplier's declaration of conformity (SDoC) versus geographies or product categories with mandatory third-party testing:



- While international trade is critical to growth, prosperity, and employment, value creation chains are becoming ever more complex, facing significant variations in safety and regulatory cultures between regions. Products that are sold in the European internal market, the United States, and worldwide must meet the relevant legal requirements and standards; they must be compliant. Independent third-party conformity assessment through competence, neutrality, and objectivity, ensures that manufacturers, trading partners, governmental bodies, and consumers can trust in the conformity of products, an integral part of well-functioning trade. TTIP should provide a framework to ensure that the level of protection to consumers' health, safety and the environment is not reduced or undermined, keeping in mind that conformity assessment procedures must only be accepted by the

other Party when they are deemed equivalent both in terms of procedure and in terms of the level of accreditation required of any (first or third-party) conformity assessment body.

PROMOTING TRANSATLANTIC TRADE AND REDUCING COSTS AND TIME TO MARKET

In a joint position paper published by ACIL, CEOC International and IFIA in June 2015[1], the conformity assessment sector came together in support of a comprehensive trade agreement that could enhance trade between Europe and the United States through the reduction of Non-Tariff Barriers to Trade (NTBs).

Given that 'mutual recognition' instruments, in the short or medium term, are not effective methods to facilitate the removal of existing barriers to trade (since they require the same standards, the same methods of conformity assessment and the same accreditation requirements) and while respecting the differences in the U.S. and EU product safety systems, this sector proposed concrete objectives to achieve seamless trading between Europe and the United States:

- Easing market access with "Cross-Border Conformity Assessment Activities" by relying on national treatment: CABs in the home location should be authorized to test and certify certain products in accordance with the legal and technical (standard-based) requirements that apply in the other economic area. Manufacturers, especially SMEs, would benefit since they could be freed to use the CAB of their choice and location most appropriate to their business model, instead of having to select from a restricted list of CABs in the destination market only.

- Streamlined transatlantic conformity assessment accreditation for all conformity assessment bodies (including first-party labs), and single market accreditation services for all CABs: accreditation is expensive and time consuming, and this is an opportunity to eliminate multiple redundant accreditations while ensuring common high-level competence of CABs, resulting in overall lower costs of compliance for manufacturers and consumers.

COMMENTS ON THE PUBLICLY AVAILABLE TEXTS: CONFORMITY ASSESSMENT PERSPECTIVES

IFIA supports negotiations that will reduce cost and speed products to the marketplace while maintaining the highest level standards and respecting the differences in the U.S. and EU 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 processes, conformity assessment, regulatory, and market authorisation requirements that differ or are not mutually recognised.

The current proposals outlined in the publicly available TTIP negotiation texts present significant concerns for IFIA and its members as the proposals do not meet the high standards which are the stated objectives of both economies in negotiating such an agreement, especially as it relates to regulatory provisions.

[1] See *ACIL-CEOC-IFIA Conformity Assessment* Perspective *on TTIP:* *http://www.ifia-federation.org/content/wp-content/uploads/TTIP_Conformity_Assessment_Paper_-_ACIL_IFIA_CEOC_-_June_2015.pdf*

Technical Barriers to Trade:

- The objective and the scope of the TBTs Chapter in TTIP should be to promote convergence in regulatory approaches by reducing or eliminating conflicting technical and conformity assessment requirements while not reducing, undermining or otherwise compromising the level of protection in public policy areas such as the protection of workers and consumers' health, public health, and the environment.

- TTIP should focus on improving the market access for all industries, including the testing, inspection and certification sector. This can be achieved by easing market access with cross-border conformity assessment activities; streamlining transatlantic accreditation; and facilitating regulatory coherence and sectoral cooperation to reduce or eliminate regulatory differences, resulting in reduced costs and time-to-market for manufacturers.

- Pursuant to not reducing, undermining or otherwise compromising, the level of protection in public policy areas such as the protection of workers' and consumers' health, public health, and the environment, conformity assessment procedures must only be accepted by the other Party when they are deemed equivalent both in terms of procedure and in terms of the level of accreditation required of any (1st or 3rd party) conformity assessment body.

- Both the EU and U.S. should endeavour to accredit, approve, license, or otherwise recognize conformity assessment bodies in the territory of the other Party on terms no less favourable than those it accords to conformity assessment bodies in its territory. To ensure that each Party accords no less favourable treatment, each Party should apply the same or equivalent procedures, criteria and other conditions to accredit, approve, license or otherwise recognize conformity assessment bodies located in the territory of another Party that it may apply to conformity assessment bodies in its own territory. This should include the exclusion of requirements for conformity assessment bodies to be located within a territory as a condition for the Party to accredit, approve, license or otherwise recognize the body or impose requirements on the conformity assessment body that would effectively require it to operate an office in the Party's territory.

- Encourage both the U.S. and EU to take administrative measures against misleading marking applied by suppliers in their territory, including false marking of compliance with standards.

Regulatory Cooperation: IFIA supports efforts to reduce or eliminate unnecessary regulatory differences through improved regulatory cooperation including working towards greater harmonisation in standards, and broader recognition and use of international standards, resulting in reductions in testing and certification costs, bringing substantial benefit to manufacturers in Europe and the United States. Regulatory cooperation must be open and transparent and should focus on harmonizing standards while respecting the different methods of conformity assessment.

Customs and Trade Facilitation: IFIA encourages both the U.S. and EU to collaborate where possible and through data sharing to take measures against counterfeit and non-compliant goods.

Intellectual Property (IP): IFIA supports efforts to provide appropriate training to customs officials to effectively combat trade in counterfeit goods, as well as an ongoing dialogue between EU and U.S. Customs authorities and promote cooperation with relevant stakeholders involved in the enforcement of intellectual property rights.

Specific Industries Annexes: IFIA believes it is important that transatlantic cooperation at the sector-specific level must be driven by the industry and have support from both sides of the Atlantic. To ensure that the level of protection of workers' and consumers' health, public health, and the protection of the environment are not reduced, undermined, or compromised, Conformity Assessment Procedures in all sectors must only be accepted into the other Party when they are deemed equivalent both in terms of procedure and in terms of the level of accreditation required of any (1st or 3rd party) conformity assessment body. In addition, IFIA believes that the inclusion of TBT-like provisions (including language on standards, inspections, market-surveillance, and equivalence) beyond the TBT Chapter that are weaker than the overarching TBT obligations sought, undermines the strength of the TBT chapter as a whole. For instance, poorly defined language in the engineering annex results in similar scope to the TBT chapter and other sectoral annexes and encroaches on TBT topics such as testing and conformity assessment. Below are additional inputs and considerations for sector-specific cooperation:

Chemicals: IFIA supports efforts to share data on chemicals where there are no risks in violating trade secrets and confidentiality. In addition, scientific cooperation is beneficial to the advancement and protection of society. The alignment of classification and labelling of chemicals based on UN GHS is critical and must be further supported by following international risk assessment procedures. Future regulatory cooperation on chemicals should include representatives from the private sector including the independent testing, inspection and certification industry, employers, workers' representatives and public interest groups such as consumers.

Energy and Raw Materials: IFIA supports the acceptance of test reports on energy efficiency issued by a laboratory accredited for such tests by an accreditation body signatory of mutual recognition agreements under ILAC, IAF and national schemes. It is important that the regulations and standards are equivalent or harmonized and that the accreditation bodies and labs are recognized by the regulators. Important to reinforce that historical and institutional differences should be respected as it relates to methods of conformity, as conformity assessment requirements have been established in response to high levels of non-compliance which put consumers at risk and create unfair competitive advantages for ethical manufacturers.

Engineering: While IFIA supports regulatory cooperation, it should only be pursued in areas where there is a clear definition of the sectoral scope and support from both sides of the Atlantic.

Medical Devices: IFIA supports the furthering of current initiatives on transatlantic cooperation. IFIA believes further regulatory cooperation must be driven by the industry and continue to operate in an open and transparent manner with participation by all relevant stakeholders including Notified Bodies. As legal harmonization and mutual recognition will be challenging in the short to medium term, a common regulatory approach by means of more intensive cooperation between the European and US authorities should be the objective. Here, a common approach to the requirements would be particularly promising in certain areas, e.g. as regards unique numbers for each medical device (Unique Device Identification – UDI) for traceability purposes. This common approach could in particular be achieved through development of new international standards and rules along with revision and uniform interpretation and use of already existing standards. A suitable environment for such cooperation would be, for example, the International Medical Device

Regulators Forum (IMDRF). Reciprocal recognition of the quality management system audits (QMS audits) is encouraged but the intensity and frequency of the regular and unannounced audits and the qualification requirements for the auditing personnel must be similar in both economic areas.

Motor Vehicles: IFIA supports the harmonization of testing procedures for vehicles, where appropriate, for instance regarding a partial harmonization of, on the one hand, EU-Directive 2007/46, the UNECE regulatory framework and, on the other hand, the Federal Motor Vehicle Safety Standards (FMVSS). However, as the conformity assessment procedures are not comparable or compatible today, a mutual recognition of motor vehicle homologation is neither yet possible nor desirable. A global conformity assessment process for vehicles is more than desirable. This will reduce costs for manufacturers, suppliers and, in the end, for consumers while guaranteeing high safety standards. These standards should rely on the existing work of the World Forum for harmonization of vehicles done under the umbrella of the UNECE and include third party conformity assessment bodies.