White Paper

Trends & Challenges for the third party TIC Sector

And its implications for CEOC International

Contents

THE TESTING, INSPECTION AND CERTIFICATION SECTOR

1. Introduction

Testing, Inspection and Certification (TIC) companies cater to a diverse range of industry sectors across the world with a variety of standards and legislation. Examples for sectors serviced by TIC company services include agriculture, automotive, commodities, consumer, environmental, food, life sciences, industrial, maritime, medical, oil & gas, petrochemical, leisure, education, systems compliance, and trade assurance. Services include quality and safety through product performance evaluations, certification and valuation of shipments, consulting, advisory, ensuring imports comply with relevant standards, industrial inspections, auditing, systems certification, supplier evaluation and laboratory outsourcing, services in the energy and transportation sectors and many more. Services provided by independent third parties can offer a number of benefits to public authorities, industry and consumers through safer products and machinery. It provides greater consumer protection, safer products and industrial installations, reduces compliance costs for SMEs and increases brand reputations and consumers' trust and confidence in a product by ensuring that products, infrastructures and processes meet the required standards and regulations in terms of quality, health and safety, environmental protection and social responsibility and can, therefore, also be a facilitator to international trade. It is important that all stakeholders involved (regulators, market surveillance authorities, manufacturers, site operators and TIC companies) have a common understanding of all the relevant standards, rules and regulations, and that mechanisms are in place to ensure compliance with the necessary requirements.

Globalisation

In a world characterised by rapid change and new technologies, energies, increasing Health, Safety, Environmental (HSE) and Quality regulations, changes to the supply chain, outsourcing and rising end user quality expectations, the TIC sector plays a key role. TIC services ensure that products, infrastructures and processes meet the required standards and regulations in terms of quality, health and safety, environmental protection and social responsibility reducing the risk of failure, accidents and disruption. Since the adoption of the General Product Safety Directive in 1995 global trade has increased many fold. Global exports increased from $5.171bn in 1995 to $15.229bn in 2010. This also resulted in an increasing number of unsafe and non-compliant products entering the European market (see the annual RAPEX reports for further information[1]). At the same time as this increase many public authorities had to cut their budgets to implement austerity programmes, thereby reducing market surveillance. TIC services can be an effective complementary solution to these developments. TIC companies adapted their services to the changes in the global supply chain and can test, inspect and certify products regardless of where in the world they are being manufactured or installed.

The TIC market

The market suggests that over the last 15 years the TIC sector has grown overall at a CAGR (Compounded Annual Growth Rate) of five to six per cent and is expected to grow further in the coming years, although this includes a wide range of variability across sub-sectors. This positive

[1] http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/index_en.htm

outlook can be attributed to factors such as strong GDP growth in the BRIC[2] countries; an increasing drive to enforce regulations by governments; international trade in products and services; and moves towards industry standardization as a result of better, more reliable and safer products, with increasing end-user awareness associating a safe business with a profitable business. This constant growth has allowed the TIC sector to meet future challenges, to continue providing competent and independent services and to follow their clients to whichever region in the world they choose to produce their products.

TIC is a €100bn global market, including both in-house and outsourced activities. Beyond the top 15 players, who account for 40% of the addressable market and who are mainly headquartered in Europe, the global TIC sector remains a highly fragmented market. It is estimated that there are many thousands of TIC companies worldwide, mostly SME/micro companies operating locally or in niche disciplines. However, they account for 60% of the market and should not be ignored.

TIC associations

Not only the TIC market itself but also the representation through associations is highly fragmented. In Europe alone, more than 20 different associations represent the TIC sector,[3] either focussing on specific services of the sector (e.g. non-destructive testing or certification) or more generally. The solution to this fragmentation is for associations to work together to raise standards and create a level playing field.

This makes particular sense as the primary aim of all these associations is very similar – the promotion of TIC services and raising standards. By working together and focussing on common goals, associations can present a stronger single voice to authorities and avoid inconsistent messages. Examples of these co-operations are the EA CAB College, where associations of conformity assessment bodies meet to discuss accreditation issues, the 4E+C meetings (representatives of Eurament, Eurachem, EUROLAB, EA and CEOC International) and joint committees, such as the joint CEOC International – EUROLAB (- IFIA) technical committee on product testing and certification (JTC PTC). These forms of co-operation should be extended into other areas and include additional associations, such as national trade associations which are members of EU or international associations.

[2] BRIC: Barzil, Russia, India and China

[3] Most, but not all of those, are based in and mainly focused on Europe, but also the international associations are trying to achieve a stronger representation in Europe.

Overview of the main European and international TIC associations[4]

The fragmentation of associations leads not only to an overlap in topics covered by the associations but also to an overlap in membership. Some of the Top 15 TIC companies are (directly or indirectly through national associations) members of up to 9 TIC associations.

Company	CEOC	IFIA	EURO LAB	EFNDT	EFAC	EEPCA	IIOC	IQNet	IACS	CIECA	CITA	CIAC	EOQ	UILI	TEAM-NB
SGS-Group	(✓)	✓	(✓)	(✓)	(✓)	(✓)	✓				✓	✓	✓	✓	✓
Bureau Veritas SA	(✓)	✓	(✓)				✓		✓		(✓)	✓	✓		
Intertek		✓	(✓)		✓	✓	✓					✓		✓	✓
DNV GL Group	✓						✓		✓						✓
DEKRA SE	✓	✓	(✓)	(✓)	(✓)	✓	✓			✓	✓				✓
TÜV SÜD AG	✓	✓	(✓)		(✓)	✓	✓				✓	✓			✓
TÜV Rheinland AG	✓	✓		(✓)	(✓)	✓				(✓)	✓	✓			✓
Applus			(✓)	(✓)							✓			✓	
Eurofins			(✓)											✓	
Lloyd Register Group	✓						✓		✓						✓
UL	✓	✓				✓					✓	✓			
TÜV Nord Group	✓				(✓)						✓				✓
ALS Limited		✓												✓	
Apave Group	✓		(✓)	(✓)											
RINA Group	✓	✓						✓	✓						

[4] ✓= direct membership ; (✓) indirect membership

2. Global Safety – The role of the TIC Sector

Trade in products and services is increasing every day and manufacturing industries, mainly outside Europe are expanding. The value chain is becoming ever more complex, and safety cultures still vary between different economic areas. Market controls have been too slow to respond to this development and this has brought about an increase of products, which do not meet safety or quality requirements. This has led to an increased political interest and public concern and created the divisive argument between quality and safety versus an open market with cheap goods and unhindered by bureaucracy. This has resulted in the demand for increased supervision and market surveillance by national governments and by local public authorities, but who may not have the capacity and resources to achieve this. The international TIC sector can respond to this at the beginning of the value chain by offering cost effective testing, inspection and certification services no matter where in the world the product is produced. By applying this preventive approach TIC services are complementary to market surveillance activities, which are random based and reactive after the products have already been placed on the market. Both instruments together ensure safe and compliant products in the market. The above demonstrates the added value of TIC services to society and justifies the foundation, professional or charitable status of the sector.

The added value of (independent third party) testing, inspection and certification

The independent TIC sector can offer many benefits to public authorities, industry and consumers. From protecting citizens from unsafe products and industrial installations, to reducing compliance costs for SMEs, to enhancing brand reputation and increasing consumers' trust into a product. To be more precise:

- Manufacturers that use safe facilities to produce safe products can save money and are in many cases more competitive because of fewer business risks (recalls, liability issues etc.) occurring. The TIC sector can provide services to support this development.
- The state ensures the safety of its citizens by making it obligatory for products with high-risk potential to be tested, inspected and certified by an independent third party.
- Consumer trust into products / services increases if there is independent proof that all relevant requirements are fulfilled.
- Third party certification and third party marks help to reduce the lack of information regarding product / service safety requirements in the market.

Why third party involvement makes a difference

Market surveillance is a very important and useful tool to take non-compliant and unsafe products off the market. However many of the market surveillance authorities are under-staffed and have not enough resources to carry out this task. 99.7% of all products entering the EU market are not checked by market surveillance authorities[5]. And among the 0.3% products that were checked more than 2000 were not in compliance with EU legislation[6]. This is where independent TIC companies can assist through their testing, inspection and certification services of new products and in-service

[5] https://www.theparliamentmagazine.eu/articles/feature/eu-council-misses-opportunity-improve-product-safety; 17 .03.2014
[6] http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_report_2014finalweb_en.pdf, p. 9

inspections of plant and machinery used at work. Unsafe products are prevented from even entering the market and machinery, which can degrade, are periodically examined to ensure they remain safe. A consumer product safety market study carried out by IFIA and CEOC International (2012, 2013 and 2014)[7] showed that 19% of the products that were self-declared compliant and CE marked had safety critical failures. In comparison with products from the same category but which had been certified by independent, accredited third party bodies, the statistic was less than 1% with safety critical failures. This market study also showed that the initial rejection rate for first-time submittals for not meeting safety requirements ranges from 27% (e.g. adapters, battery chargers) to 63% (white goods). These are products that manufacturers presented having passed their own quality and safety checks. Without third party involvement these products would have been placed on the market.

Shared responsibility for ensuring safe and compliant products

We should however be careful in drawing conclusions from these statistics. There are a number of major brand manufacturers, who have the resources and competence and fully understand the need for ensuring quality and safety in their products. The TIC sector associations should work closely with manufacturers associations to promote a common approach and raise standards. In particular identify the smaller manufacturers who primarily assemble components to make a product, but do not necessarily have the competence or resources to carry out adequate testing for safety. This is the market where the TIC companies can add value and operate successfully.

To provide a high level of safety, especially for consumers, the above outlines impressively the need for close co-operation of all parties involved, i.e. regulatory market surveillance, manufacturers and third parties, in particularly the more complex, high risk products, whose failure could cause injury damage or worse.

3. The TIC sector position on….

…. a harmonised and well-functioning accreditation system

A harmonised and credible accreditation system is of great importance for the TIC sector. Accreditation is the method of ensuring competence in delivering conformity assessment activities, such as testing, inspection and certification. Such a system must be based on harmonised requirements (and a harmonised application of these requirements), be transparent, efficient and authoritative. Accreditation needs to enable a fair competition among accredited TIC companies on a global market. This will be compromised if the application, interpretation of the necessary requirements and competences of assessors varies between national accreditation bodies. As such accreditation bodies and TIC companies should also work closely together in order to have a common understanding of the procedure.

An inquiry conducted by EUROLAB members reflecting the practices of EA members noted an inconsistency and variation of average time interval between the following on-site visit after the first surveillance of between 15 months and two years. Increasing the frequency of surveillance visits did not result in any improvement of the overall quality of laboratory work – but it did cause additional

[7] http://ceoc.com/documents/The%20added%20value%20of%20independent%20product%20testing_Marcello%20Manca.pdf

costs for those laboratories (and consequently for their customers). Another potential concern is the need for better coordination among accreditation bodies when it comes to cross-frontier accreditation and assessment. The original idea of this policy was to reduce the administrative burden for TIC companies that are active in several countries but – at least in Europe - the opposite happened and the system is now so bureaucratic that few TIC companies use it. Instead most multinational TIC companies continue to have their local entities accredited by local Accreditation Bodies, resulting in multiple accreditations from various Accreditation Bodies, even though these local entities work under the supervision of the head office and under the same quality system and management.

Whenever possible the setting of accreditation rules and guidance should be a top-down process, i.e. the documents are developed on an international level and are then transposed into the European / regional and national system. This will ensure a level playing field on a global scale. TIC companies need global accreditations that are accepted everywhere in order to be able to provide the necessary services to their clients.

The active participation of TIC sector representatives in the various committees and working groups of EA, ILAC, IAF and of the national accreditation bodies is of great importance. This participation allows the TIC sector to monitor developments at an early stage and to work towards a common approach, while at the same time upholding the good relations between accreditation and conformity assessment bodies. Voting rights for stakeholders, as they are already custom in IAF and some national accreditation bodies, should also be introduced in EA and ILAC, to give all involved parties greater influence. In addition a greater role should be given to stakeholder committees such as the EA Advisory Board (EAAB). Structures should be put in place ensuring that stakeholders can have de facto impact on the accreditation organisations' decisions and policies.

… the developments concerning ISO / IEC standards

As international standards describe the requirements to be fulfilled by conformity assessment bodies active involvement in standardisation is an essential task for TIC companies. Representation and participation of TIC experts on national, European and international level is therefore strongly encouraged. The coordination between these three levels becomes ever more important as most of the standards that apply to TIC companies are now being developed at an international level (ISO / IEC) and are then being translated into European and national standards. As stakeholders on the international and European level TIC associations do not have voting rights but can participate in the various working groups and submit comments, sometimes on behalf of a TIC association, sometimes as the representative of the national standardisation body. As such, a coordinated approach is needed and regular exchange of information between TIC companies, through associations should be supported.

As with accreditation, so it is also with standardisation that a harmonisation approach should be pursued. If standards are being referred to in European and national legislation then these standards should be harmonised ones, in particular when it comes to the ISO / IEC 17000 series.

… the European Conformity Assessment System

The "New Approach" has been in existence as a recognised set of rules for the marketing of products within the European internal market for more than 25 years. Products falling within the scope of the New Approach directives or regulations may basically only be put into circulation if they bear the CE marking. The party responsible for putting the products into circulation is the manufacturer. By applying the CE mark to his products, he declares that they are in compliance with the relevant legal provisions, and in particular with its essential health, safety and environmental requirements.

Depending on the risk potential of the products, either the manufacturer alone is responsible for the conformity assessment procedure, or a notified body must be involved. A notified body is an independent inspection and certification body which reviews the conformity assessment performed by the manufacturer and testifies to its correctness based on unified evaluation criteria. The independence and competence of the notified body is guaranteed by means of national notification (normally mandated through accreditation) in the individual EU Member State; designation and surveillance of Notified Bodies is performed by the relevant state authorities.

The overall system of the New Approach with its corresponding EC directives and the conformity assessment procedures embedded in them has proven its worth. In order to continuously improve and to further develop health and consumer protection in Europe a focus should be placed on enforcement and harmonised application of the set of rules. With respect to the conformity assessment procedures, the role of the Notified Bodies within the overall system as independent control and surveillance bodies must be strengthened, and their competences should be assured accordingly. Well designed and applied processes and procedures lead to effective inspection and control of products and installations, thus ensuring their compliance.

<u>In general the TIC sector proposes the following improvements:</u>

- Augmenting the current Notified Bodies system by promoting and supporting the European accreditation system.
- Mandatory third party testing of products in accordance with the risk assessment, e.g. Class III medical devices or toys for children under 3 years, certain electrical goods.
- Inclusion of Notified Bodies in the information flow of market surveillance authorities.
- Notified Bodies should be used more extensively to complement market surveillance activities and ensure
    - better testing and certification before a product is placed on the market and / or recognition of voluntary marks;
    - identification of counterfeit products and / or certification.

<u>More specific:</u>

- *Industrial Products*[8]*:*
    - A profound and reliable post-evaluation of the functioning of the implemented legal provisions, as foreseen in the initiative for "Better Regulation" of the European

[8] based on the *CEOC Position paper on the Communication from the Commission "A vision for the internal market for industrial products" COM(2014) 25 final, 22.1.2014*

Commission is not sensible until the NLF has been completely transposed in the relevant regulations and directives and subsequently, where necessary, into national law. A fundamental evaluation of the overall effects, benefits and even weaknesses of the NLF should only be conducted after the newly adopted and modernized product legislation has been in force for at least several, preferably ten, years at the minimum.

  - Transforming Decision 768/2008/EC into a horizontal regulation would *not*, as is claimed, reduce the volume of the current legislation. Different product legislation will always be necessary because the legal requirements for products must consider the potential risks, uses and consumer markets.

- *Market Surveillance Regulation*: consultation by / participation in the to-be established Market Surveillance Forum (Art. 25 MSR).
- *Introduction of a voluntary 'EU Safety Tested Mark'*: in case that attempts will be made again in the future to introduce a Europe-wide safety mark, this mark needs to be based on a robust system, fulfilling the following requirements:
  - The principles of accredited product certification must be fulfilled in accordance with the harmonized Standard ISO / IEC 17065:2012 "Requirements for bodies certifying products, processes and services".
  - The Mark must be based on a type examination of the product, a conformity evaluation and decision on conformity of the product with specified requirements relating to product safety, followed by on-going production monitoring.
  - To facilitate traceability and enhance transparency in the market, the mark of the "accredited independent third party body" should be linked to the new Mark. The accredited independent third party body, as owner of its mark, is in the position to undertake the necessary protection measures when a product bears the Safety Mark in combination with this mark without proper authorisation.
  - In accordance with Directive 1999/34/EC and 85/374/EEC for defective products and Decision 768/2008 on a common framework for the marketing of products, manufacturers are liable for the products placed on the market and their compliance with community requirements. Accredited independent third parties are liable for conformity assessment activities such as testing, inspection or certification.
  - The mark needs to be properly explained and marketed in a coordinated manner so that manufacturers, suppliers and consumers properly understand its value.

… the Transatlantic Trade and Investment Partnership (TTIP)

- Building trust and facilitate market access - "Making TTIP a success" with the means of transatlantic conformity assessment (one-stop-shopping).
- The instruments "legal harmonization" and "mutual recognition" in short or medium term not as appropriate to remove the existing barriers.
- One accreditation body for both markets (one-stop-shopping) – efficient proof of competence.
- Uniform conformity mark from independent, accredited testing laboratories for marketing of products in both markets – creating transparency and identity.

For the above to work the scope of application needs to be clearly defined in order to establish:

- A common approach to risk evaluation to identify the types of product considered. Among others these would include toys, low-voltage devices, machinery, measuring instruments, radio equipment and telecommunications terminals, and also sports boats. This scope should be periodically reviewed to cater for changes in technology and experience in the market.
- This scope shall only apply insofar as both contractual parties (EU and the US) delegate authority to non-governmental bodies for the task of conformity assessment in the respective product groups.
- The scope does not apply where one of the contractual parties (EU or US) delegates authority to one single private body with a monopoly for the task of conformity assessment in the respective product group.

Additional requirements:

- Utilisation of independent CABs when evaluating the equivalence of product requirement.
- Establishment of a uniformly structured and transparent standardisation system.
- Consistent application of internationally accepted standards without adding additional requirements.
- Unrestricted, non-discriminatory market access – in theory and in practice.

… relations with other stakeholders

Creating alliances with other stakeholders is an important task for associations. The more stakeholders support a message, the stronger the message gets. Natural allies for the TIC sector are consumer and manufacturers' associations. Together we all want to see only safe products on the market, which means that we support every effort for a well-functioning set of rules bringing products into the market. This includes the necessity of a well-funded, homogenous market surveillance framework across the EU in order to prevent rogue operators from having access to the market. CEOC International has established very good relationships with all relevant stakeholders.

4. CEOC International as the recognised voice of safety and quality

The aim of CEOC International and its members is to be the recognised voice of safety, compliance and quality in Europe and world-wide. But in order to achieve this goal continuous self-assessment is required. As with many brand manufacturers, the TIC sector relies heavily on its reputation. It is the trust in the competence and independence of TIC companies that is crucial.

TIC companies must be valued for their contribution to the improvement of quality and their role for making sure that the liberalisation of trade is not detrimental to health, safety and environmental protection. They assist industry in bringing "good" products to the market and in ensuring the fairness of competition in a global economy. Legislators and authorities can promote this development by supporting the need for independent assessments and by strengthening the role of the TIC sector in the global supply chains.

List of Abbreviations and Acronyms

ANEC	the European consumer voice in standardisation
BEUC	European Consumer Organisation
BRIC	Brazil, Russia, India, China
CAB	Conformity Assessment Body
CAGR	Compounded Annual Growth Rate
EA	European Co-operation for Accreditation
EM	Emerging Markets
EURACHEM	European Association for Analytical Chemical Laboratories
EURAMET	European Association of National Metrology Institutes
EUROLAB	European Federation of National Associations of Measurement, Testing and Analytical Laboratories
GDP	Gross Domestic Product
HSE	Health, Safety, Environmental
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IFIA	International Federation of Inspection Agencies
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standardisation Organisation
NLF	New Legislative Framework
SME	Small and medium-sized enterprise
TIC	Testing, Inspection and Certification