

Standards and Conformity Assessment Challenges faced by Industry

International trade has observed a growth in past few years. The growth has led to challenges for industry as there is rise in the number of national and international voluntary standards, technical regulations, and conformity assessment procedures which apply across all market sectors to products, services, processes, management systems or personnel. Generally, these are introduced to meet the legitimate requirements of quality and safety that consumers, businesses, regulators and other organisations demand in the case of goods and services, whatever their country of origin. It is vital, not only for individuals and organisations but for national and international economic health, that products and services can cross borders to meet global demand without causing undue risk to the health and safety of individuals or the environment. However, there are challenges faced by industry related to standards, regulations and certification due to varying requirements, lack of proper understanding, absence of suitable infrastructure etc.

In the WTO regime, there are two distinct sectors: sectors amenable to Technical Regulations and sectors driven by Standards (Voluntary). Technical Regulations are the responsibility of the Government which are made in the interest of the country and its consumers whereas Standards, which are voluntary, are driven by market, industry and other stakeholders.

Technical Regulations lay down requirements for product characteristics or their related processes and production methods, **compliance to which is mandatory**. Keeping in view the WTO Agreements, member countries can impose Technical Regulations on grounds such as health, safety, environment, deceptive trade practices, and national security. Regulations have to be the same for imports as well as locally manufactured goods based on the principle of national treatment, so that imports are not blocked due to differential regulations. WTO encourages countries to adopt international standards as Technical Regulations so as to avoid barriers and most developed countries adopt International Standards as Technical Regulations. Standards higher than International Standards can be adopted as regulations by giving proper scientific justification and this provision is currently utilized by many developed countries increasing the challenge for our industry.

Challenges faced by the Industry with respect to Technical Regulations are that Industry has to first and foremost comply with domestic regulations. Typical examples are in sectors such as Food, Drugs, Electrical Appliance, and Electronic and IT Goods, In many sectors, Technical Regulations are non existent in India in many sectors – such as Machinery, Toys, Personal Protective Equipment etc and in some sectors such as Food and Pharma, they are short of International Standards.

The next challenge for the Industry is to comply with Technical Regulations of the importing countries if it wishes to export. Goods will be denied entry if these Technical Regulations are not complied with and typically these are more stringent than domestic regulations and require extra effort by the Industry for compliance. While Pharma, Automotive and Seafood sectors are successful examples, industry in most other sectors struggle to comply with the Technical Regulations of importing countries.

Therefore, there is a need for a system that importing countries can recognize – such as recognition of EIC for Seafood Exports by the European Commission. This will avoid plant by plant audit and save huge compliance costs. Such a system is encouraged by SPS and TBT Agreements too and is needed for other sectors such as Pharma. We need to work in this direction to make it easier for our industry.

Standards provide the rules, guidelines or characteristics for products or related processes and production methods and **compliance to these is voluntary as opposed to compliance to Technical Regulation which is mandatory**. Voluntary Standards are typically developed by the National Standards Bodies that are mostly governmental in developing countries and yet standards developed by them are voluntary. In most developed countries, standards bodies are private bodies having strong connect with industry. Sometimes buyers may demand these Standards and therefore it may be necessary for Industry to adopt these. Voluntary Standards include ISO and IEC Standards such as ISO 9001, ISO 14001, etc and these are a growing tribe.

Standards and Technical Regulations may include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements.

There is another category of what are called the **Private Standards** which are developed by stakeholders like retailers, industry etc. These Standards may offer protection against liability which is important even as global sourcing grows and they also address concerns about Social issues such as child labour, wages, workers' safety etc. Some examples of Private Standards are Global G.A.P for Agri produce, Forest management (FSC/PEFC) for legality of wood and sustainable forest management, WRAP for Textiles, BRC for Food and other Social and labour Standards.

Some Private Standards are also industry driven like automotive (IATF 16949), TL 9000 in Telecom, AS 9100 in Aerospace which are driven by the need to upgrade suppliers. The major concern about these Private Standards is that they are not always participatory or transparent. Some of them are also used in regulated sectors such as Food, labour etc and can be a challenge to the industry.

Meeting these regulations and standards is however not enough. Industry has to gear up to face challenges beyond compliance to Technical Regulations and Standards. It is no longer enough to merely comply to these but the manner of demonstrating compliance to these is also equally important. There are a variety of conformity assessment models or routes available starting from the least stringent one -self declaration of conformity to the intensive third party assessment.

Conformity assessment is growing in importance. A WTO study of Specific Trade Concerns (STCs) raised in the TBT Committee indicated that only 30% of the STCs are based on Standards while 70% of the STCs are on Conformity assessment procedures. This is understandable because more and more countries today are adopting International Standards and standards then cease to be an issue; however their Conformity assessment procedures differ and will continue to differ.

Conformity assessment is demonstration that **specified requirements** relating to a **product, process, system, person or body** are fulfilled and includes activities such as **testing, inspection and certification**, as well as the **accreditation of conformity assessment bodies**.

A typical example of how compliance to International Standards alone is not enough and that the conformity assessment process is equally important, is the case of Tyres manufactured in India, complying to International Standards, regulated in India by BIS and yet not accepted by a small country like Ecuador, only because Ecuador has prescribed a certificate of conformity from a Certification Body accredited by the National Accreditation Body of the country of origin, which in this case happens to be NABCB and BIS is not accredited by NABCB. Similarly, several other products are not going to Ecuador for the same reason – absence of Certification Bodies accredited by the National Accreditation Body

In view of the above, it is clear what the emerging quality infrastructure should look like and roles are becoming clearly defined as follows:

- Government to enact legislation and make policies;
- Regulatory bodies to enforce the law on day to day basis Regulators can be sector specific like food, drugs etc.;
- Standards bodies to make voluntary Standards and may provide standards to regulators also;
- Accreditation bodies to confirm the technical competence of Conformity Assessment Bodies (CABs);
- Conformity assessment bodies to support regulations, voluntary standards and quality assurance by verifying conformity to various Standards, Regulations etc;
- Manufacturers and service providers to provide goods and services which are reliable with global acceptance, and
- Common consumers, who are the recipients of goods and services.

In the wake of this, what we need to do is as follows:

- a. Adopt International Standards wherever they exist both for industry and conformity assessment and if possible have standards/technical regulations that are higher than International Standards.
- b. Reorganize Quality Infrastructure as per International Best Practices ensuring that regulations are the responsibility of Government, Standards are increasingly to be left to stakeholders and Conformity Assessment is to be left to non governmental sector, distanced from Government
- c. Ensure role separation between the activities of making Regulations, Standards setting, Conformity Assessment, Accreditation and Capacity Building or Training.

To conclude, it is important for the Industry to understand what are Technical Regulations and what are Voluntary Standards and the difference between the two. It is also important for Industry to understand that Regulations are the law of the land – and will prevail over voluntary standards even if voluntary



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Standards are made by Govt. or Govt. bodies like BIS. While Regulations are focussed on health, safety etc, voluntary standards can focus on quality and promote excellence. Industry has to be ready to meet the challenges of both technical regulations, standards and conformity assessment present in the market.