

S A F E T Y



Standards

Inspections

Accreditations

Certifications

Regulations

Testing



CHALLENGES OF STANDARDS AND CONFORMITY ASSESSMENT

Part - 1



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INTRODUCTION

With the advent of WTO regime in 1995, the tariff and quantitative barriers in international trade have gone down and what are called non-tariff barriers have come to occupy the centre stage. The major barriers among nontariff barriers are acknowledged to be those related to **standards and conformity assessment**.

The WTO regime recognizes that the governments have a **right to protect their populace** on grounds such as health and safety and therefore can impose product requirements by law – called **technical regulations** or **sanitary and phytosanitary (SPS) measures** in agrifood sector. In fact, it prescribes under the **Agreement on Technical Barriers to Trade**, commonly called the **TBT Agreement**, grounds such as **health** (food, drugs, medical devices), **safety** (toys, electrical appliances, LPG cylinders), **environment** (emission levels in vehicles, environmental laws, lead content in paints), **deceptive trade practices** (adulteration in cement or gold jewellery) and **national security** (telecom equipment) for regulation i.e. product requirements imposed by law.

This has led to **rise in the number of technical regulations, national and international voluntary standards, and conformity assessment procedures** which apply across all 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 stakeholders 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.

The WTO regime has thus led to creation of **two distinct segments**: one, comprising sectors amenable to **Technical Regulations/SPS measures** and another comprising sectors driven by **Standards** (which now are defined to be *per se* Voluntary). Technical Regulations/SPS measures are the responsibility of the Government which are notified in the interest of the country and its people whereas Standards, which are voluntary, are usually driven by market, industry and other stakeholders.

Any business, including MSMEs and startups, therefore need to not only be aware of the regulations and standards which apply to the sector in which they operate but also assimilate these in the product or service at the design stage itself so that their product or service meets the regulatory requirements, which are mandatory, to survive and standards prevalent in the market and demanded by buyers to succeed.

REGULATIONS

Technical Regulations lay down requirements for product characteristics or their related processes and production methods, **compliance to which is mandatory** as defined in the TBT Agreement. 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/SPS measures so as to avoid barriers and most developed countries adopt International Standards as Technical Regulations/SPS measures. 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 Indian industry.

First and foremost challenge is to **comply with domestic regulations** depending on the sector one operates in. Typical examples are sectors such as Food, Drugs, Electrical Appliances, Electronics and IT Goods, Cement, Telecom products and Steel products. In many sectors, regulations are non-existent in India but currently coordinated by the Department of Commerce, an exercise is on to bridge this deficit in regulations. Sectors such as Machinery, Toys, Medical Devices, Personal Protective Equipment, and Chemicals are in the process of being regulated. **As a thumb rule, if one's product has health or safety implications, he should expect to be regulated.**

The next challenge for the Indian industry is to comply with **regulations of the importing countries** if it wishes to export. This challenge is compounded in some sectors such as Food and Pharma, where domestic regulations are short of International Standards or Machinery or Medical Devices or Chemicals where India is currently largely or totally unregulated. Goods are denied entry if these regulations are not complied with and typically these are more stringent than domestic regulations requiring extra effort by the Industry for compliance. While Pharma, Automotive and Seafood sectors are successful examples where India has achieved global standards and accessed global markets, industry in most other sectors struggles to comply with the regulations of the importing countries. The challenge is even greater for MSMEs or start-ups with the resource constraints they obviously face.

VOLUNTARY STANDARDS

The next challenge is that of voluntary standards prevalent in the market. Standards provide the rules, guidelines or characteristics for products or related processes and production methods and

compliance to these is voluntary as defined in the TBT Agreement as opposed to **compliance to Technical Regulations 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, national standards bodies are private bodies having strong connect with industry and clear separation between regulations and standards exists. The **Bureau of Indian Standards (BIS)** is the national standards body of India with over 20000 standards including 12000 plus product standards and any entrepreneur setting up a business or in business looking for building quality is well advised to look at BIS standards available for his product or service as the first point of reference, if its not a regulated sector.

In many sectors, even in regulated sectors, buyers demand certifications to these standards and therefore it becomes necessary for Industry to adopt these. Voluntary Standards include international standards of the **International Organization for Standardization (ISO)** and **International Electrotechnical Commission (IEC)** such as ISO 9001 for quality management systems (QMS), ISO 14001 for environment management systems (EMS), ISO 45001 for occupational health & safety management systems (OHSMS), ISO 27001 for information security management systems etc and these are a growing tribe.

There is another category which is industry driven like IATF 16949 **automotive sector** (), TL 9000 in **Telecom**, AS 9100 in **Aerospace** which are driven by the need to upgrade suppliers to major players and OEMs in these sectors and if one operates in these sectors, they have become almost obligatory.

Yet another important category is of what were called the **Private Standards**, now increasingly being called **Voluntary or Private Sustainability Standards (VSS or PSS)**, which are developed by stakeholders like retailers, industry, non governmental organizations etc. These standards may offer **protection against liability** which has become important even as global sourcing grows and/or they may address concerns about **social issues** such as child labour, fair wages, workplace safety etc. or **environmental compliance** or even **food safety.** Some examples of such 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/IFS/FSSC 22000 for Food and other Social Standards like SA 8000. These standards pose a challenge in terms of both capacity of Indian industry, especially MSMEs and start ups to implement as also the cost of compliance in the form of certification to these standards.

There are Indian schemes available now e.g Ind GAP or India HACCP by QCI or Forest management certification by NCCF at much lesser cost and if any of these are benchmarked internationally (e.g. NCCF), they facilitate exports as well. The industry would be well advised to look at the Indian schemes first to reduce cost of compliance for them.

Note :

Part 2 of this article will cover about International Conformity Assessment Structure, Recognition of Conformity Assessment, Role of Accreditation, Emerging Global Scenario in the next month's issue.