Introduction to Draft Indian National Strategy for Standards (INSS)

Department of Commerce has been engaged in organising various standards conclaves since 2014 so as to address the issues concerning regulatory eco-system in the country in a structural manner. Till now 4 national and 10 regional standard conclaves have been organised, where various stakeholders, like producers/exporters of agricultural, marine products along with those in industrial goods and services have participated and shared their constraints and suggestions. State governments and various regulatory ministries/ departments/ organisations have also deliberated upon likely strategies to strengthen regulatory regime in the country and equipping exporters with information on technical barriers they face in foreign markets. During the last (4th National Standards Conclave, 1-2 May 2017 at New Delhi), a draft strategy paper titled Indian National Standards Strategy (INSS) that was prepared as an outcome of last four years activities was discussed. The draft was also subsequently discussed with subject experts on various other fora, and now, a draft final strategy document has been readied.

Key objectives of this draft strategy are following:

- Positioning standards as a key driver of all economic activities relating to goods and services.
- Developing a comprehensive ecosystem in India for standards development taking into account the diversity of interests and expertise available
- Using standards as enhancer of competitiveness of Indian goods and services in domestic and international markets.
- Providing level playing field to domestic industry
- Adopting best practices in standardization, conformity assessment, and technical regulations, and creating an integrated infrastructure, roadmaps and institutions for their effective management.
- Playing an active role and taking leadership positions in apex international forums in the related areas
- Creating response mechanisms to global developments on standards, technical regulations, and conformity assessment practices that impact market access of Indian goods and services
- Aligning the Strategy with other national policies related to trade & industry, consumers and environment.

Comments /inputs on strategy document may be sent to the e-mail address: tpdmoc@nic.in by 30th March 2018 (i.e. within 30 days).

Indian National Strategy for Standardization

DRAFT

Prepared by

TPD/DoC

Indian National Strategy for Standardization

Foreword

The rapid growth of the Indian economy, its size and emerging relevance in global trade, makes it essential to establish a robust 'Quality Infrastructure' in India with a harmonized, dynamic, and mature standards ecosystem. This would fuel economic growth and enhance the 'Made in India' label. Standards have been widely recognized as catalysts for technical development, industrial growth, well-being of the society and more recently for convergence of new and emerging technologies. The growing influence of standards and technical regulations, and corresponding conformity assessment systems on trade and commerce has been recognized worldwide through the TBT, SPS and GATS agreements of WTO. Countries are accordingly evolving strategies to synergize standardization work with technological, social and economic development at the national level as well as for playing influencing roles in global standardization efforts.

The Indian National Strategy for Standardization (INSS) considers the current state of development across sectors, the existing quality infrastructure and the policy directions in relation to domestic economic developments and for trade in goods and services.

This INSS is the result of a broad consensus arrived over consultations held over a four-year period from 2014 to 2017 through national and regional standards conclaves that attracted wide participation of experts and stakeholders from union and state governments, industry, regulatory bodies, national and overseas standards and conformity assessment bodies, academics, and international forums.

Scope and Approach

The INSS addresses three broad pillars of the Quality infrastructure, viz Standardization, Conformity assessment, and Technical Regulations. It determines the critical role for each and sets goals in each area. Each goal is supplemented by a brief description of the background conditions and recommends specific activities that need to be undertaken for its realization. It takes into account the needs and expectations of all stakeholders, and accords the interests of MSMEs a high consideration.

The Strategic Intents

The INSS provides direction for India's political and executive leadership on how best to use standardization and the quality infrastructure to advance the interests and well-being of Indians in a global economy. It is based on the following considerations:

- Positioning standards as a key driver of all economic activities relating to goods and services.
- Developing a comprehensive ecosystem in India for standards development taking into account the diversity of interests and expertise available
- Using standards as enhancer of competitiveness of Indian goods and services in domestic and international markets.
- Adopting best practices in standardization, conformity assessment, and technical regulations, and creating an integrated infrastructure, roadmaps and institutions for their effective management.
- Playing an active role and taking leadership positions in apex international forums in the related areas
- Creating response mechanisms to global developments on standards, technical regulations, and conformity assessment practices that impact market access of Indian goods and services
- Aligning the Strategy with other national policies related to trade & industry, consumers and environment.

Implementing the INSS

The INSS is intended be a living document with an implementation plan to ensure positive outcomes in each of the identified area. Some of the recommended tasks in the INSS do not currently fall under direct jurisdiction of any of the existing organizations. Once approved, an implementation plan would be prepared identifying the agencies, the related activities to be undertaken by them and the time frames.

While some of the goals and the related activities can be accomplished over a shorter period, it is expected that all elements of the strategy can be undertaken and completed over a five-year period (2018-2023)

The implementation plan would be monitored by a high-level committee with quarterly reviews and the results of the monitoring with the achievements will be published on the India Standards Portal.

Standards development

Vision: *Building a national culture of standards for growth and economic leadership*

Mission: *Developing a dynamic, relevant and priority driven standards ecosystem that will drive development across sectors, promote competitiveness of Indian products and services, and foster India's eminence among the global leaders in standardization*

Goal 1: Convergence of all standards development activities in India

India's standards setting process has been led by the Bureau of Indian standards (BIS), the national standards body, since 1947. Additionally, to a limited extent, sector specific standardization work is carried out by more than 25 other bodies including ministries, regulatory bodies, public sector undertakings, technical development agencies, commodity boards etc. More recently overseas standards development organizations have established offices in India with a view to engage experts and to support industries using their standards.

- Enhance capability of SDOS for dynamic and faster development of standards, matching with the pace of technology development
- Encourage setting up of new SDOs in emerging technology areas with international connects
- Adopt the SDO standards as National standards when required
- Set up an accreditation scheme for SDOs
- Avoid duplications and overlaps
- Ensure market relevance of standards produced at all times

While BIS develops Indian standards through its sectional committees under 14 Division Councils representing sectoral interests, based on the international code of practice for standards development, the other SDOs essentially rely on dedicated expertise for standards writing and follow their own procedures. A system to recognize or integrate their standards as national standards does not exist presently.

With a view to broad base and enhance the pace of the standards setting activity, it is essential to enhance the capacity and resource base of the existing SDOS and also to encourage the setting up of new SDOs in new and emerging areas and cutting-edge technologies notably digital technologies, sustainable practices, clean energy and smart cities. These SDOs must have connections and working arrangements with the respective international bodies to ensure there is no gap in the availability of standards to Indian industry.

The Bureau of Indian Standards shall remain the apex national standards body and as per the mandate of the BIS ACT, 2016 continue to oversee the harmonious development of standardization activities under its own umbrella as well as through memorandum of understanding with the other SDOS that would include the adoption of their standards as national standards as and when required by national needs and priorities. Such arrangements would ensure that there is no duplication or overlap in the standardization activities of multiple agencies. It shall remain their joint responsibility to ensure at all times that the standards in force

are relevant, and reflect the state of the technology and industrial practices through appropriate market surveys, environmental scans and comparative studies with the standards being developed worldwide.

An accreditation scheme for SDOs shall be established to ensure that they implement the ISO / WTO codes of practice for standards development.

Goal 2: Setting up a dynamic mechanism for new standards identification, development and their updation

Over the past 70 years more than 20000 Indian standards have been developed, almost 50 % of which are product standards and the rest are support standards such as test methods, terminology, codes of practices etc. The subject matter for taking up new standards or for adoption of international standards is decided by the respective Division Councils and Technical Committees of BIS, while the other SDOs take similar decisions through committees or through executive decisions.

- Make standardization a key priority area across all sectors
- Set up dialogue forums and processes to articulate and prioritize needs for standards development
- Create opportunities for Indian business through standards
- Focus on critical sectors linked to economic, social and sustainable development

The present system does not present full opportunity or channels for articulation of needs by all potential standards users. As a consequence, there is widespread use of standards developed by overseas bodies without their adoption in India. There are also large gaps where no standards exist for use, especially in the service sector. In several areas, only guidance standards or codes exist but not the related product standards.

There is an urgent need to create forums and processes to articulate and prioritize needs for standards development in different sectors. The best candidates for articulating the needs are the ministries and policy forums under them, the related industry bodies and the commodity boards wherever present. A standards forum needs to be set up in each of these bodies that would be responsible to set up stakeholder consultations and dialogue forums with businesses and professional bodies and MSMEs to identify the gaps, to collate the needs and to coordinate with BIS and the relevant SDOs for a time bound development or revision of the required standards.

The prime considerations during stakeholder consultation would be identification of technologies, and the markets and industry sectors in which standardization can create opportunities for Indian business.

Some of the key areas in which standards need to be developed on priority are Information technology, sustainable technologies and practices, the underprivileged and marginalized sectors, industrial automation, safety of machinery, tourism, healthcare, education and skills

Goal 3: Inclusive participation of all stakeholders in standards development including States and MSMEs

Effective standards development requires adequate and continuous participation of all interest groups and subject matter experts. In order to achieve this, it is important to generate widespread intertest and awareness in the standards programmes being undertaken by BIS and other SDOs and to attract participation, with financial support where funding becomes the restriction especially for MSMEs and civil society groups.

The Standards Conclaves initiated in 2014 have served as good forums to inform and educate on the relevance of standardization, conformity assessment and technical regulations. There is a need to continue holding more Standard Conclaves at the Central and State levels on rotational basis. The National Institute of Training for Standardization of BIS should be made responsible for creating training and awareness modules for enhancing awareness up to District levels and industrial clusters.

- Enhance awareness on the role and benefits of standards and conformity assessment practices among businesses, government and civil society including consumers
- Creation of States and District forums for standards related activities
- Set up Funding mechanisms to supplement participation costs

Over time the standards building process should become a layered activity with inputs invited and collated from States and District standards forums. Depending upon the intensity of the industrial or economic activity, the Standards committees should give representation for direct participation to these forums.

The funding assistance by Central Government for participation in standards development activity should be broad based and made more liberal, to fund participation of MSMEs, individual subject matter experts, nonprofit bodies and civil society groups both in national as well as international standards committees. State Governments must be encouraged to create matching funds to sponsor participation.

Goal 4: Integrating and harmonizing all standardization work with international and market driven standards

The need for harmonizing Indian standards with international standards for reducing technical barriers to trade and improve market access for Indian products and services, cannot be overemphasized. In order to ensure that Indian businesses remain competitive both in domestic and overseas markets, the goods and services must conform to globally accepted standards. While national considerations for specific local considerations, such as climatic and cultural

conditions, should be given due accord, these should be minimal and least restrictive. As BIS is the official member body of ISO and IEC and Department of Telecommunications the official member of ITU, they need to undertake a systematic and time bound programme for adopting and aligning all Indian standards with the corresponding international standards. The principal focus should be on product / equipment / hardware standards with concomitant adoption of related codes of practices, test methods and protocol standards.

- Harmonize national standards with international standards
- Align national standards with market driven standards
- Special focus and pooling of expertise on converging technologies

Apart from standards developed by the ISO, IEC and ITU, it is widely recognized that standards developed by professional private bodies such as ASTM, ASME, IEEE, GlobalGap, OneM2M have significant market presence and user base. BIS and other SDOs engaged in the respective domains need to ensure that their standards do not present conflicts to industry and businesses and to explore arrangements for alignment with the private standards, especially where there is some form of compulsion on conformance to the national standards.

The advancement of ICT and digital technologies in all spheres of manufacturing and service domains will be throwing new challenges for standard developers. This will call for convergence of multidisciplinary expertise into more and more standards projects in future. Participation from industry having access to international developments in these projects would be imminent. Close collaboration among BIS, Telecommunications Engineering Centre (TEC) and Telecommunications Standards Development Society, India (TSDSI) would be required to create the necessary synergies and avoid duplication of work.

Goal 4: Identifying sectors where India could pioneer standardization work

Historically, the Indian standardization effort has been following standards developed by other standards bodies. India offers many sectors with significant commercial potential that have remained outside the scope of standardization. Undertaking pioneering standardization work in these areas would not only unleash their commercial potential but also enhance India's contribution to global standardization efforts. These areas can include the Indian system of alternative medicines, yoga, ayurvedic traditional healing services, Indian food cuisines, traditional crafts etc.

- Develop pioneering standards in areas of traditional strength
- Develop service standards on a time bound programme
- Develop innovative and cutting edge standards based on Research & Development

The development of service standards is still in its early stages worldwide. With major contribution to Indian and global economy coming from the services sector, there is substantial potential for standardization of services, especially those with export potential. Services standardization work needs to be taken in a structured manner and a time bound programme with the simultaneous development of horizontal and vertical standards. This will require participation of central and state agencies as well as service providers. The key areas for service standards development are healthcare, tourism, education and skills.

With a view to develop cutting edge standards that can propel Indian businesses as leading suppliers in the global markets, concerted efforts are required to develop innovative standards based on original research and development. Unlike traditional approach, these standards would be torch bearers and lead commercial development.

Goal 5: Systematic and continuous participation in international standardization work

Participation in international standard setting projects enables the voicing, consideration and possible inclusion of national priorities and concerns. With increased adoption of international standards by the global community, these are becoming de-facto universal standards impacting competitive positions. It is therefore essential that they do not contain provisions that place Indian suppliers at a disadvantage and this can be secured only through continuous participation of experts who understand both the technical requirements as well as their impact on trade and commerce.

- Ensure continuous participation in international standards committees by identified experts through liberal funding support
- Take leadership roles in technical committees and governance structures
- Play an active role in development of private standards

An essential pre-requisite is the continuity of participation during the lifecycle of the standards project. A firm policy needs to be in place to ensure positive participation in every standard project that is identified to be in India's interest. Each standard body, regulator and the related Ministry should identify the international forums related to it, and the committees where India's participation on standards setting or compliance mechanisms is essential. For each of these forums, the participation plans should be drawn synchronized with the annual calendar of meetings and suitable technical experts identified for continuous participation. The experts can be drawn from industry, or scientific bodies or in individual capacity. The fund allocation by government should fully cover the costs for participation in international standards development activity with simplified procedures that allow automatic funding based on agreed principles.

Continuous participation should be gradually translated into taking leadership positions on international standards and project committees as well as governance structures, and winning secretarial responsibilities commensurate with India's position as a leading global economy.

With the increasing influence of private standards, participation in the related forums should be sought and attended following a similar approach as for international forums. Some SDOs invite participation of individual experts. A coordination mechanism needs to be developed under the aegis of BIS to ensure that the individual experts participating in these bodies from India are appropriately sensitized about national priorities and needs.

Goal 6: Support and facilitate development of Regional SAARC Standards

The South Asian Regional Standards Organization (SARSO) was established in 2010 to achieve and enhance coordination and cooperation among SAARC Member states in the areas of standardization and conformity assessment with the objective to develop harmonized Standards for the region, to facilitate intra-regional trade, and to enhance access in the global market for the SAARC Region suppliers. There has been limited progress in the development of the SARSO standards. Being the leading economy of the Region, India should play an active role in providing leadership both in the development of the standards as well as in trade negotiations for market access of South Asian products and services on behalf of the SAARC member countries.

Conformity Assessment

Vision: *Evolving a credible, competent and robust infrastructure for conformity assessment that stimulates a quality mindset nationwide*

Mission*: Provide confidence to customers and markets, supplement and provide alternates to regulatory oversight and escalate Indian exports*

Goal 1: Enhance credibility of conformity assessment programmes in domestic and overseas markets

The opening up of the Indian economy led to the simultaneous development of a national quality infrastructure that now includes a full complement of conformity assessment schemes comprising third party inspections, product certification, management systems certification, testing and calibration, self-declaration of conformity, personnel certification. Conformity assessment services are being provided by dedicated government appointed organizations, private conformity assessment bodies (CABs), and in some cases directly by the regulatory bodies. In the same period, the national accreditation boards have enhanced their scopes and consolidated their outreach by accrediting all the major CABs. A significant number of CABs

- Encourage all conformity assessment bodies to get accredited by national accreditation boards
- Set up a market surveillance agency to monitor conformity claims both under regulation and self-declarations
- Encourage and recognize voluntary self-regulation mechanisms for delivery of credible conformity assessment services as alternate to regulations

however still operate outside the register of the national accreditation boards that presents gaps in their oversight and accountability. As self-compliance levels are still below par, it is important that the entire conformity assessment infrastructure operates with demonstrated high integrity to inspire confidence among domestic and overseas buyers and regulators. Concerted efforts should be made through suitable incentives and mandates to bring all conformity assessment operators within the fold of national accreditation.

Presently, there are limited means for post market testing of the actual level of conformance of the products placed in the market, especially those that are under self-declaration of conformity. As more and more products are expected to be brought under technical regulations, there is a need to establish a national market surveillance agency that would be responsible to monitor conformity of products placed in the market, whether certified or regulated under self-declaration of conformity. The results of such surveillance would provide valuable inputs for impact assessment and on the effectiveness of the conformity assessment programmes.

While accreditation boards are responsible for ensuring the competence and independence of the CABs, a supplementary means to raise credibility of conformity assessment is by creation of self-regulating, self-managed mechanisms that take responsibility for monitoring the integrity and reliability of the conformity assessment programmes and the CABs that operate them. Responsible CABs and laboratories need to develop such voluntary self-regulating mechanisms and create market pressure for all operators to subscribe to them. The development of such credible mechanisms would reduce the need to regulate and allow markets to operate freely.

Goal 2: Secure and enhance global equivalence through mutual recognition agreements in accreditation and sectoral forums across a broad range of goods and services

Significant achievements have been made by the national accreditation boards NABCB and NABL in gaining full membership status across a range of multilateral recognition arrangements in accreditation of conformity assessment programmes within the IAF and ILAC umbrella. This enables the meeting of minimum qualifying criteria for market access by certified products and services within the fold of such accreditations. However, in most cases, regulatory requirements of importing countries require additional conformance conditions that need to be met through equivalence recognition arrangements. These apply in diverse fields including food, pharma, chemicals, toys, medical devices, electrical and IT equipment, telecommunication equipment as well as services such as ITES, education and skills certification. It is necessary to map the entire spectrum of products and services that need to meet specific conformity assessment requirements and to systematically install and develop facilities and infrastructure that would help achieve equivalence status. As the body directly responsible for export certification, this initiative should be led by the Export Inspection Council and supplemented by the export promotion councils, commodity boards, accreditation boards and the CABs operating in the respective areas.

Goal 3: Restructuring the ISI Mark Scheme for promoting Indian products across global markets

Promotion of Indian products in overseas markets needs to be backed with a visible and credible *Made-in-India* certification label that gives assurance of quality and sustainable practices. The ISI Mark scheme of BIS is founded on sound principles of conformity assessment (product certification) and is time tested to be the best candidate for international certification labeling. However, in its present form it is restricted by legal boundaries in terms of territorial application as well as criteria for certification which is limited to Indian standards. The BIS also has limitation of resources for operating the

- Upscale the ISI Mark Scheme to a Made-in-India Certification label
- Certification to Indian, international and importing country standards
- Brand promotion by export promotion organizations, industry bodies, missions

scheme. In order to expand the scheme for a global audience it needs to be significantly enlarged from its current scale and operated on professional lines at par with some of the leading global certification programmes. This would entail the following changes:

a. To enlarge the resource base, the scheme should be opened up for participation by multiple certification bodies who would be empaneled and authorized by BIS as the scheme owner to issue certification for exports and would need to be accredited by NABCB.
b. Certification for exported products should be offered to Indian, international and importing country standards as per need
c. Multiple routes for product, process and service certification should be available permitted by relevant ISO CASCO Standards

Once the scheme is in place, it should be actively promoted by export promotion organizations, industry bodies, overseas missions with funding assistance from Government for brand promotion.

Goal 4: Minimize costs of conformity assessment, especially for MSMEs to make them globally competitive

There is an urgent need to ease the compliance burden of MSMEs in meeting regulatory and overseas market access requirements. Both Central and State Governments have been providing funding assistance for securing Quality Management Systems certification based on ISO 9001 and in some sectors, such as food testing, costs to set up laboratories. Since compliances are typically based on testing, inspections and product certification, the financial assistance needs to be extended to all types of conformity assessment within the allocated budgetary provisions.

- Extend the funding assistance for MSMEs to all types of conformity assessment
- Promote NABCB/ NABL accredited conformity results and domestic equivalent approvals for acceptance by overseas regulators and organized foreign buyers
- Set up common testing facilities for MSME clusters

The compliance burden can be further reduced by negotiating with overseas regulators and buyers to accept domestic testing, inspection and certification results backed by accreditation provided by NABCB and NABL. Where capability approval is a pre-requisite, Export Inspection Council and the Export promotion boards need to set up robust inspection programmes and seek approval of overseas regulators or organized buyers that would authorize them to issue certificates of conformity on similar lines as already achieved in some sectors.

As costs of testing equipment is a major burden on MSMEs, State Governments need to identify common needs especially where MSMEs are present in clusters and assist by setting up common testing facilities that can be run on cooperative basis.

Goal 5: Enhancing awareness regarding conformity assessment among stakeholders

With a fairly large quality infrastructure existing in India, comprising of multiple forms of conformity assessment programmes and schemes, it is essential that there is widespread awareness of the scope and purpose of these programmes, creation of understanding of how each form of conformity assessment can be selected and applied, the role and importance of accreditation, the bodies responsible for delivering the conformity assessment and accreditation services, and where and how complaints, disputes and appeals can be raised. It is also necessary to create awareness of specific sectoral conformity assessment requirements imposed through global schemes that have an impact on exports. The target audience for building awareness should include officials responsible for policy and technical regulations, the enforcement agencies, the buyer agencies both under central and state governments, officials responsible for port controls and trade associations. The awareness campaigns should be joint responsibility of the accreditation boards and the apex industry associations with assistance from the State government academies of administration.

Goal 6: Active participation in ISO CASCO, IAF and ILAC

India is a participating member of ISO CASCO. A mirror committee has been set up by BIS with participating members drawn from accreditation boards, industry, SDOs, PSUs. CASCO standards have a deep impact on the manner in which conformity assessment programmes are mandated to run worldwide. However due to cultural differences, the presence or absence of requirements impact the effective implementation of these standards. It is absolutely essential to participate in all CASCO working groups by the relevant agencies and attend all their meetings to ensure that India's viewpoints are raised and incorporated in the standards developed.

As the accreditation Boards are automatic members of IAF / ILAC they also need to ensure that they participate in all meetings of these apex organizations.

Whenever opportunity arises, the constant policy should be to occupy leadership positions on the technical committees, working groups and governance structures in these apex bodies.

Technical Regulations

Vision: Securing the highest degree of protection for the well-being and safety of Indian citizens

Mission: Ensuring that technical regulations are a last resort to alternative forms of market control, are minimal, risk based, least burdensome and effective in meeting the purpose with least disruption to businesses

Goal 1: Evolving a mature understanding of good regulatory practices and regulatory impact

- Adopt Good regulatory practices and issue policy guidelines for development, implementation, review and revision of Technical Regulations and regulatory impact assessment
- Create understanding among agencies responsible for notifying and ensuirng compliance to technical regulations
- Conduct regulatory impact assessment for all technical regulations

As regulations are issued to protect and balance the needs of civil society and its various interest groups, they need to be precisely calibrated to the risks in context with the times, entail minimal cost burden, should be easy to comply, and be transparently administered. They must not impede economic growth and social development. Inappropriately applied technical regulations may lead to higher prices of goods and services, lack of product innovation and poor service quality. As regulations have the tendency of losing relevance with time, they need to be regularly recalibrated for effectiveness and purpose.

All technical regulations should be based on the principles of good regulatory practices that include risk based selection of regulatory measures, considerations of regulatory efficiency, i.e. balance between costs of compliance and administration versus gains; effectiveness in compliances; transparency in notification, administration and changes; openness in communications and balancing of interests.

Technical regulations should also be assessed for impact on benefits against costs, economic burden on government, and impacts on competitiveness of industry, market openness, small businesses, public sector and potentially affected social groups.

Policy guidelines based on Good Regulatory practices and Regulatory Impact Assessment need to be established for the development, implementation, review and revision of Technical Regulations.

It is also necessary to create a thorough understanding of the importance of following good regulatory practices and regulatory impacts among ministries, regulatory bodies, state

governments, enforcement agencies, conformity assessment bodies and social groups. Civil Services Academies should initiate awareness courses and workshops on the subject.

Goal 2: Separation of regulatory roles from policy development and conformity assessment

Regulatory functions typically include registration of manufacturers, enforcement of the technical regulations which may involve conducting search and seizure operations, prosecuting non-compliant manufacturers as well as market surveillance in terms of picking up samples from the market and testing them to ensure the requirements of the technical regulations are complied with. These functions need to be maintained completely independent from other interests such as sectoral or trade development typically discharged by ministries, or conformity assessment / accreditation that involves payment of fees, as these present characteristic conflicts. Presently such overlap of roles exists among many agencies.

A review needs to be done to identify all agencies discharging dual functions for systematic separation of roles who should retain only the essential function and delegate the conflicting role to other bodies.

Goal 3: Ensure protection of consumers, animal, plant, environment, industrial workers through suitable technical regulations in areas that are commonly and widely regulated worldwide

Comparative studies of products and services regulated in India with majority of other countries have revealed significant gaps both in terms of `numbers as well as the technical requirements to which they must conform. Absence of technical regulations adversely impact the protection of consumers, animal, plant and environment from unregulated sub-standard products and services produced or imported into India. Inflow of substandard products which are typically cheaper, also impact the competitive position of responsible producers, many of whom have

- Identify gaps between India and global practices on technical regulations notified
- Identify gaps between India and global practices on technical requirements (standards / essential requirements) included in technical regulations
- Eliminate the gaps through a systematic plan

selected voluntary certification. It is also recognized that minimum compliance levels enhance sectoral capabilities and export potential.

It is essential to conduct a gap analysis of areas where major gaps exist in Technical Regulations notified by majority of countries but absent in India and to systematically eliminate the gaps, while applying the principles of good regulatory practices and impact assessment.

A review of requirements notified in Indian technical regulations compared to global practices also needs to undertaken for suitable modifications where significant gaps are determined.

Goal 4: Technical Regulations should be based on appropriate standards and conformity assessment method based on market conditions and attendant risks

Technical regulations invariably create a burden of compliance on the producers and suppliers of products and services with attendant costs that are borne throughout the supply chain including the consumer, as well as government in running the enforcement programmes. Regulators therefore need to carefully select the most essential requirements in products, processes or services that would serve the purpose of the regulations. While adoption of standards professionally developed by standards bodies should be the first preference, regulators must be proactive in the development and revisions of such standards and ensure that their scope should be restricted to aspects of safety and security in line with the

- Technical regulations must specify minimum essential requirements and be based on established standards or essential requirements drawn by technical experts
- Technical regulations must select the least burdensome route of conformity assessment that is capable of covering the risks
- Technical regulations should be finalized only after wide stakeholder consultation

regulatory intent. Where quality standards are intended to be regulated for deceptive trade practices, the standards should contain performance requirements and should not restrict input materials or process routes. Regulators should also ensure that the standards used for regulations are adopted or closely harmonized with international standards. In cases, where essential requirements are directly incorporated in the technical regulations, these should be drawn by empaneled experts.

Technical regulations should select conformity assessment routes that are least obtrusive and burdensome to cover the breadth and magnitude of the safety, security or deception risks. Presently regulations that rely on conformity assessment as the means for compliance have, with a few exceptions, chosen product certification routes operated by BIS or by the regulators themselves, which impose the highest cost of compliance. As several other conformity assessment routes are available such as self-declaration of conformity, design certification, batch certification, third party inspection, sample testing, capability approvals, these should be examined for best suitability before selection. The first preference should always be accorded to

self-declaration of conformity, but these should be combined with adequate prior and post market testing, and backed by stringent penal provisions in case of willful default.

Technical regulations should be finalized only after wide stakeholder consultation and fulfilment of WTO notification obligations.

Goal 5: Create an overarching regulatory instrument and oversight mechanism for technical regulations and conformity assessment

Presently technical regulations are notified under different Acts, and under the BIS Act where no sector specific Act is existing. These Acts have been drafted to serve specific purposes and are limited in scopes. It is essential to enact a new enabling legislation for notifying standards, technical regulations and conformity assessment procedures in accordance with global good regulatory practices with suitable surveillance and enforcement provisions including imports. This legislation should apply to all those sectors that are presently not covered by sector specific regulations, and should have provision for establishing independent regulators as needed. It should also include provisions for regulatory impact assessment and periodical reviews and sunset clauses.

Suitable regulatory instrument is also required to protect consumers against unsupported claims of conformity by suppliers or conformity assessment bodies that are not accredited and therefore not accountable.

Goal 6: Create an effective market surveillance mechanism

Presently market surveillance activities and other enforcement measures are handled by State Government agencies and customs officials at the ports who are not best equipped in terms of technical understanding, resources and empowerment. As the requirements for post market surveillance and testing including cyber intelligence are expected to increase in future it is necessary to establish a professional agency for carrying out or coordinating all market surveillance and port control operations. Market surveillance should invariably include testing of products drawn from the market and in cases of willful deceptive practices, statutory actions to prevent further supplies.

Goal 7: Creating response mechanisms to overseas technical regulations, private standards, and conformity assessment practices that impede market access of Indian goods and services

New and revised technical regulations are being regularly notified by countries classified as TBT and SPS notifications. Many of these have a direct or indirect impact on supply of Indian goods and services. An urgent need exists to develop a dynamic and responsive mechanism that would trigger anticipatory as well as post notification responses. As a first step, institutional arrangements are required to scan all new notifications, bring them to the knowledge of the

impacted suppliers, including potential suppliers, collate their concerns and issue timely national responses to the notification. The role of the subject matter ministries is critical in appraising the issues and drafting the national responses.

Post notification responses include understanding the impact in terms of resources, technology readiness, and quality infrastructure required to meet the compliance requirements. Depending on the magnitude of impact, subject matter ministries, relevant departments and bodies under them should prepare an impact document indicating the assistance at the government level that should be provided, especially to the MSMEs.

INDIA QUALITY INFRASTRUCTURE