

Regulatory Practices in India

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REGULATORY REQUIREMENTS IN INDIA

- To safeguard health and safety, Government of India promulgates regulatory requirements for manufacture and sale of goods and services, including those imported
- Regulations are stipulated through Various Acts/ Rules & Regulations by different Ministries under Government of India
- Enactment of Acts, Rules & Regulations is done taking cognizance of the relevant WTO Agreements



REGULATORY REQUIREMENTS- Key Considerations

- Regulatory measures should be minimum required
- Regulatory measures should have minimum compliance costs
- Regulatory measures should benefit society
- Regulatory measures should comply with the laws of the country



REGULATORY REQUIREMENTS- Key Considerations (contd)

- Regulations should be made & enforced in a transparent manner
- Regulations should be fair and treat all equitably
- Regulations should be drafted in clear and simple language for understanding of all
- Regulatory measures should be flexible for amendments/ revision , if required due to changed circumstances



FOREIGN TRADE – QUALITY REGULATIONS IN INDIA

- **FOR IMPORTS:**

- Directorate General of Foreign Trade
- Relevant Regulatory Agency
- BIS for 68 Products

- **FOR EXPORTS:**

- Export Inspection Council



SOME ACTS/ REGULATIONS/ CONTROL ORDERS TO REGULATE TRADE IN INDIA	AGENCIES INVOLVED
>Prevention of Food Adulteration Act 1954 >(on the pattern of USFDA)	Directorate General of Health Services
>Plant Quarantine (Regulation of Import into India) Order, 2003	Department of Agriculture & Cooperation
>Insecticides Act	Deptt. Of Agriculture and co-operation
>Fruit Products Order, 1955	Ministry of Food Processing Industries
>Meat Food Product Order 1973	Ministry of Food Processing Industries
>Milk and Milk Product Order 1992	Directorate General of Health Services
>Standards on Weight and Measurement Act 1976	Department of Legal Metrology
>Bureau of Indian Standards act, 1986	Department of Consumer Affairs, Govt. of India
>AGMARK Act 1937	Directorate of Marketing and Inspection



SOME ACTS/ REGULATIONS/ CONTROL ORDERS TO REGULATE TRADE IN INDIA	AGENCIES INVOLVED
>Drugs & Cosmetics Rules	Ministry of Health & Family Welfare
>Textiles Regulation 1988	Ministry of Textiles
>Export (Quality Control and Inspection) Act, 1963	Export Inspection Council of India
>Indian Explosives Act, 1884	Chief Controller of Explosives
>Mines Act	Directorate General of Mines Safety



ACTS/ REGULATIONS/ CONTROL ORDERS To regulate trade through Mandatory Certification by BIS	PRODUCTS
Prevention of Food Adulteration Act 1954	Infant Milk Products, Packaged Drinking Water and Natural Mineral Water
The Infant Milk Substitutes, Feeding Bottles and Infant Foods (regulation of production, supply and distribution), Act	Plastic Feeding Bottles
Bureau of Indian Standards Act, 1986	Electrical Wires, Cables, Appliances and Protection Devices and Accessories
Indian Explosive Act, 1884	Gas Cylinders
Bureau of Indian Standards Act, 1986	Clinical Thermometers
Essential Commodities Act, 1955	Pressure stoves, Steel Tubes
Environment (Protection), Act 1986	Compression ignition (diesel) engines
Bureau of Indian Standards Act, 1986	Cement



BUREAU OF INDIAN STANDARDS

- INDIAN STANDARDS INSTITUTION [now known as BUREAU OF INDIAN STANDARDS(BIS)] set up on 6 JANUARY 1947
- BIS is functioning under MINISTRY OF CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION, GOVT OF INDIA as a statutory body under BIS ACT, 1986 with effect from 1 APRIL 1987
- NATIONAL STANDARDS BODY of INDIA
- OBJECTIVES
 - Harmonious, development of standardization and quality control in national and international arena
 - Certification schemes for products and systems
 - Growth and development of Indian industry, commerce and exports
 - Consumer protection



APPROACH TO STANDARDIZATION

- Standards formulated by BIS are primarily, voluntary in nature
- Through various Acts/ Regulations, out of the more than 18 000 standards formulated so far, only 68 standards are subject to Mandatory Certification



**TECHNICAL COMMITTEE
STRUCTURE
(Members From)**

Manufacturers

**Consumers,
Government
Departments**

**Technologists , Regulating
Authorities, Testing
Laboratories, Consultants,
Universities, Other Experts**

BASIC APPROACH

Consensus Principle

**Balanced
Committee
Structure**



STANDARDS FORMULATION- BASIC STEPS

- Accepted Code of Good Practice of TBT Agreement
- International standards/ their relevant parts are used in standards setting
- However in case of fundamental technical/ geographical/ climatic problems, standards are set as per national requirements
- As NSB BIS takes full part in the development of International Standards, relevant to the national needs.

STANDARDS FORMULATION- CONSENSUS & TRANSPARENCY

- All standards are widely circulated at draft stage
- Period of comments is generally not less than 3 months,
- For urgent reasons pertaining to safety, health or environment, period can be reduced
- Drafts documents are hosted on BIS website for public comments
- All comments are duly considered by the appropriate authorities
- Programme of Work is published and also hosted on BIS website and is periodically updated



STANDARDS FORMULATED

OVERVIEW

- INDIAN STANDARDS PUBLISHED - 18315
- CORRESPONDING ISO/IEC STANDARDS - 5821
- STANDARDS HARMONIZED WITH ISO/IEC STANDARDS
(About 76%) - 4449
- DIVISIONAL COUNCILS 14
- TECHNICAL COMMITTEES 301
- TECHNICAL EXPERTS 11750
(Sec. Com+ Sub Com+ Panel)



CONFORMITY ASSESSMENT PRACTICES



CERTIFICATION ACTIVITIES OF BIS

- Operating under an Act of Indian Parliament (BIS Act 1986)
- Offers third party assurance
- Based on well defined scheme of testing and inspection
- Ensuring adequacy of in-process quality control



CERTIFICATION ACTIVITIES OF BIS (contd.)

Supported by:

Testing Laboratories

- BIS Labs
- Other Labs

Accreditation under National Laboratory Accreditation Scheme according to ISO/IEC 17025

Traceability to APLAC/ILAC.



CERTIFICATION SCHEME

Based on Type 5 of ISO Guide 28 which includes:

- Type testing and assessment of factory quality control and its acceptance followed by
- Surveillance that takes into account audit of factory quality control, and
- Testing of samples both from factory and open market



CERTIFICATION SCHEME FOR FOREIGN MANUFACTURERS

- Scheme for Foreign Manufacturers
 - 93 licences granted in 16 countries such as France, UAE, South Korea, Nepal, Switzerland, Thailand, Bhutan, China, etc.
 - Products certified include Packaged Drinking Water, Cement, Wood Products, Steel Products, Milk Products, Clinical Thermometers, Energy Meters, Electrical Appliances & Switchgear items etc.



Regulations & Their Notification



NOTIFICATION PRACTICES

Criteria for notification includes assessment of:

- whether international standard exists or technical content differs from international standards
- impact of regulation on trade
- whether regulation deals with technical requirements or SPS measures for a product/group of products (relevance under the TBT and SPS Agreements)

Various sources that are consulted:

- TBT Agreement, and relevant Committee recommendations and decisions
- regulatory agency responsible for the regulation



NOTIFICATION PROCEDURES

PREPARATION

- Initiated by regulator of proposed legislations
- Complete notification format by the Regulatory Body in consultation with Ministry of Commerce
- Clear and descriptive outline of the regulatory proposal
- Give adequate time to comment on the proposal
- Reasonable time for adoption of measure

SUBMISSION

- Prepared notifications are sent to WTO Central Registry of Notifications (CRN) by National Notification Authority



MOUs/ MRAs- TOOLS FOR REGULATORY COOPERATION

BIS has signed MOUs with 15 countries with a view to

- Enhance cooperation in standardisation & conformity assessment
- Facilitate sharing of expertise and mutual trade

MRA with SRILANKA :

- Trade Facilitation



INDO US COOPERATION INITIATIVE

INDO US Portal is a commitment by BIS & ANSI to:

- Provide common platform for required transparency
- Facilitate sharing of information on trade issues
- Provide mutual support at international fora
- Facilitate harmonisation of Standards & Conformity Assessment Procedures through increased transparency



REGIONAL COOPERATION INITIATIVES

Establishment of SARSO (South Asian Regional Standards Association)

Objectives:

- Coordination & Cooperation between SAARC countries in standards & Conformity Assessment
- Develop harmonised standards
- Facilitate intra regional trade
- Promote MRAs on conformity assessment



THANK YOU

