# 10

# Technical Regulation

## 10.1 INTRODUCTION

A technical regulation is "a document which lays down product characteristics or their related processes and production methods, including applicable administrative provisions, with which compliance is mandatory" (WTO 1995, annex 1). The administrative provisions are normally considered to include conformity assessment, responsibilities of the regulatory authority, and sanctions. Technical regulations are therefore legally binding prescription and must be applied by all parties.

Authorities, when developing and implementing technical regulations, must comply with the provisions of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) if the country is a WTO member. National and foreign suppliers must comply with the technical regulations developed and implemented by the regulatory authorities concerning the products they market in the country, and authorities have a surveillance responsibility to ensure that suppliers do so.

The elements of technical regulation as defined in the WTO TBT Agreement include technical requirements and administrative provisions. The former should be based on international standards, and the latter are normally considered to include the conformity assessment provisions, regulatory authorities, and sanctions. (See module 7 of the QI Toolkit, for a comprehensive discussion.) Good regulatory practice requires a coordinated approach to all of these at the national level, which would be given legal standing in a technical regulation framework. The pillars and building blocks of a technical regulation regime, as shown in table 10.1 and detailed in this Comprehensive Diagnostic Tool, are based on such good regulatory practice.

To depict the pillars and building blocks in a graphical way that would indicate the state of technical regulation in a country at a glance, they can be put together as shown in figure 10.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

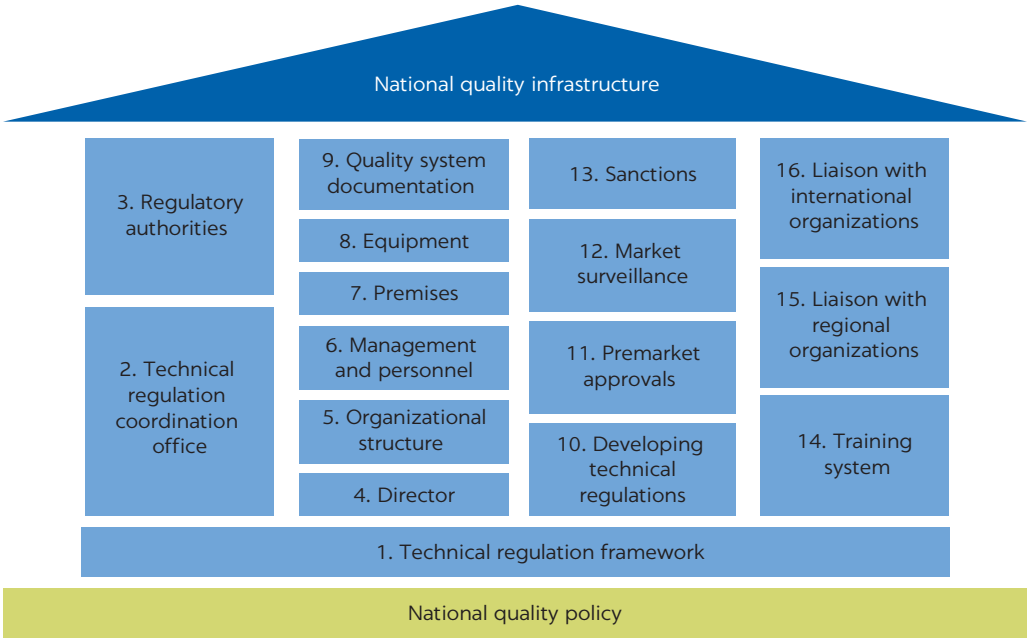
(*Note:* Legal metrology is part of technical regulation, but it is dealt with separately; see section 11: Legal Metrology.)

**TABLE 10.1 Pillars and building blocks of a country's technical regulation regime**

| PILLAR | BUILDING BLOCK NO. | BUILDING BLOCK DESCRIPTION |
|---|---|---|
| 1: Legal and institutional framework | 1 | Technical regulation framework |
| | 2 | Technical regulation coordination office |
| | 3 | Regulatory authorities |
| 2: Administration and infrastructure | 4 | Director |
| | 5 | Organizational structure |
| | 6 | Management and personnel |
| | 7 | Premises |
| | 8 | Equipment |
| | 9 | Quality system documentation |
| 3: Service delivery and recognition | 10 | Developing technical regulations |
| | 11 | Premarket approvals |
| | 12 | Market surveillance |
| | 13 | Sanctions |
| | 14 | Training systems |
| 4: External relations and recognition | 15 | Liaison with regional organizations |
| | 16 | Liaison with international organizations |

*Note:* The term "technical regulation regime" denotes the broader collection of sometimes quite different approaches to technical regulation in a country, whereas a technical regulation framework is a common approach followed by all the regulatory authorities. The European Union (EU) New Approach and Global Approach Directives are typical technical regulation frameworks.

**FIGURE 10.1**
**House of technical regulation for a national quality infrastructure**




*Note:* The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

## 10.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK

### 10.2.1 Benchmark and significance

Technical regulation is the responsibility of government and its competent authorities. Government should enact the necessary legislation to establish a technical regulation framework that will guide the development and implementation of technical regulations across all ministries and regulatory authorities. Its development is frequently also dealt with in a national quality policy (see module 10 of the QI Toolkit). Without such a technical regulation framework,

- Each ministry and regulatory authority will continue to develop and implement technical regulations in their own way, which may or may not comply with the WTO TBT Agreement; and
- Coordination between regulatory authorities and between those authorities and the quality infrastructure (QI) service providers will suffer, and costly and unnecessary overlaps or gaps will develop over time, potentially rendering local suppliers uncompetitive and compromising the safety and health of the country's people, fauna and flora, and the environment.

Regarding the coordination of technical regulation, a technical regulation coordination office (or a similar facility) should be established at the highest appropriate political level to (a) coordinate the responsibilities of the various regulatory authorities—and to coordinate them as well with the QI service providers—to minimize overlaps; (b) ensure compliance with the WTO TBT Agreement and requirements; and (c) ensure the development and implementation of an effective and efficient technical regulation regime within the country.

The number of regulatory authorities is dependent on the customs and practice of the country, the size of the market, and resource constraints. In many countries, every ministry establishes the number of regulatory authorities it deems necessary; in some countries, the number has been reduced to four or five sectorally focused regulatory authorities, and in small economies, only one supraregulatory authority responsible for all technical regulations has been established. The first option is expensive but politically acceptable; the last option is financially efficient but politically challenging.

### 10.2.2 Technical regulation framework (building block no. 1)

***What is meant***

| | |
|---|---|
| Fundamental | A technical regulation framework is enshrined in legislation that provides guidance for all the modalities of the development and implementation of technical regulations across all ministries and regulatory authorities at the national, regional, and local levels. |

***How can it be demonstrated?***

The technical regulation framework should detail all the modalities for the development and implementation of technical regulations by all ministries and regulatory authorities at the national, regional, and local levels. Details that should be covered include the following:

- Regulatory impact assessments (RIAs)
- The use of international, regional, or national standards as the basis of technical regulation

- The use of technically competent and designated conformity assessment service providers
- The responsibilities of regulatory authorities regarding premarket approvals, in-market surveillance, and the imposition of sanctions
- Administrative and legal sanctions

The technical regulation framework should be a legislative instrument, such as an act of parliament, that takes precedence over any other legislation that may authorize ministries or regulatory authorities to develop and implement technical regulations. The technical regulation framework must comply with the requirements of the WTO TBT Agreement if the country is a WTO member, as well as with regional TBT agreements, protocols, or legislation, if relevant. Its promulgation must be notified to the WTO TBT Secretariat if the country is a WTO member.

***Existing information/reporting/monitoring***

- Relevant legislative instruments, such as acts of parliament
- Relevant ministry papers
- WTO TBT notifications of the country

### 10.2.3 Technical regulation coordination office (building block no. 2)

***What is meant***

| | |
|---|---|
| Major | Technical regulation is complex, even at the national level. A technical regulation coordination office should be established at the highest political level to coordinate technical regulation activities of the regulatory authorities among each other and with the QI service providers. |

***How can it be demonstrated?***

In many countries, a number of ministries and regulatory authorities develop and implement technical regulations. To minimize overlaps and gaps in their responsibilities and actual regulatory work, a technical regulation coordination office (however named) should be established at the highest political level necessary to enforce such coordination (see module 7 of the QI Toolkit). This office should also coordinate the interfaces between the regulatory authorities and the other QI service organizations to ensure the optimum usage of standards, metrology, accreditation, and conformity assessment services in the development and implementation of technical regulations.

***Existing information/reporting/monitoring***

- Technical regulation framework act or similar law
- Technical regulation coordination office records

### 10.2.4 Regulatory authorities (building block no. 3)

***What is meant***

| | |
|---|---|
| Fundamental | The regulatory authorities must be recognized entities, and their sphere of responsibility must be clearly defined to minimize regulatory overlaps and gaps. |

***How can it be demonstrated?***

Whatever the number of regulatory authorities, they should be clearly identified in the technical regulation framework, and their spheres of responsibility should be properly and uniquely defined to minimize regulatory overlaps and gaps regarding the products they are responsible for. In other words, the technical regulations they are responsible for must be assigned to them. This information has to be publicly available to safeguard against confusion in the marketplace.

The number of regulatory authorities may be reconsidered during a regulatory reform process (see module 7 of the QI Toolkit). The optimum number of regulatory authorities is as much a resource issue as it is a political decision. If changes are contemplated (reducing or expanding the number), then care should be taken that, during the changeover process, the implementation of the relevant technical regulations does not suffer.

***Existing information/reporting/monitoring***

- Technical regulation legislation
- Official ministerial decisions
- National WTO TBT Inquiry Point information[1]

## 10.3 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

### 10.3.1 Benchmark and significance

The implementation of technical regulations has two sides: First, suppliers must demonstrate that the products they wish to place on the market comply with the technical requirements of the technical regulation. Second, the regulatory authority has the responsibility to monitor the products in the marketplace to ensure that suppliers market only compliant products.

The demonstration of compliance may be a self-declaration of conformity by the supplier, or it may be by inspection, testing, and certification of third-party conformity assessment service providers. These third-party providers should be technically competent and acceptable to the regulatory authority (that is, "designated").

(*Note:* The third-party assessment service providers are not considered in this section, but they are discussed in the sections on accreditation, inspection, testing, and certification [sections 5, 6, 7, and 8, respectively]. The same applies to the regulatory authority as the conformity assessment body. This section is dedicated to the regulatory authority's oversight responsibilities to ensure that suppliers and products comply with technical regulation requirements.)

In some economies, the regulatory authority conducts such conformity assessments as required by the technical regulation, but in general that is no longer seen as good regulatory practice for these reasons:

- The regulatory authority can quickly become obsessed with testing and retesting to bolster its budget income, and hence may neglect its market surveillance responsibility.
- The regulatory authority may create the perception that it, not the supplier, is responsible for the integrity of the product.

- Final product testing, especially on an audit sample basis, is not an ideal way of ensuring that all of the production complies with requirements; the whole production value chain has to be considered.

Using the national product certification mark for the final product testing is no longer seen as good practice, either, because it is considered to be trade-restrictive and arguably contrary to WTO TBT Agreement principles.

The regulatory authority is responsible for monitoring the compliance of products with technical regulations. These responsibilities include the premarket approval of high-risk products, market surveillance of all products falling within the scope of technical regulations, and the imposition of sanctions when nonconformities are discovered. The regulatory authority will also test products as an audit sample at irregular intervals to verify the conformity assessment evidence provided by the supplier. Because of the regulatory nature of its responsibilities, the regulatory authority will of necessity have to be a government-type organization in most jurisdictions, unless such regulatory powers can be conferred on a private sector organization in terms of national legislation.

### 10.3.2 Director (building block no. 4)

***What is meant***

| | |
|---|---|
| Major | The regulatory authority must be managed by a director (whatever the actual title) who is accountable for the compliance of products in the marketplace that fall within the scope of the technical regulations the regulatory authority is responsible for. |

***How can it be demonstrated?***

There is no standardized list of the major functions and responsibilities carried out by the director of a regulatory authority, but some typical functions include the following:

- Supports operations and administration of the relevant ministry by advising and informing its members, interfacing between the ministry and staff
- Oversees the design, marketing, promotion, delivery, and quality of services with regard to technical regulation implementation
- Recommends the annual budget for ministry approval and prudently manages the regulatory authority's resources within those budget guidelines according to current laws and regulations
- Effectively manages the human resources of the regulatory authority according to authorized personnel policies and procedures that conform with current laws and regulations, especially the training and appointment of inspectors
- Assures that the regulatory authority and its mission, programs, and services are consistently presented using strong, positive images to relevant stakeholders, including the relevant minister and ministry
- As the responsible executive, considers the premarket approval of high-risk products, where relevant, and initiates sanctions when nonconforming products are uncovered in the marketplace
- Liaises with third-party conformity assessment service providers, where relevant
- Oversees fundraising planning and implementation, including identifying resource requirements, researching funding sources, and establishing strategies to approach funders

***Existing information/reporting/monitoring***

- Relevant technical regulation legislation
- Official ministerial decisions
- Official director job description
- Agreed-upon director key performance indicators

### 10.3.3 Organizational structure (building block no. 5)

***What is meant***

| | |
|---|---|
| Fundamental | The organizational structure of the regulatory authority must facilitate the effective and efficient execution of all technical regulations it is responsible for, and it should have divisions that optimally support these groupings and their subject fields. |

***How can it be demonstrated?***

The regulatory authority is usually a government department or a statutory body, rarely a private sector organization. As a government department, it can rely on support services, such as government finances and human resources, whereas if it is an independent public sector organization, it has to provide for these itself.

Technical regulation authorities deal primarily with trade-related issues, and preventive components include premarket approval of high-risk products. The repressive component consists primarily of market surveillance. Premarket approval is mostly a head office activity, whereas the market surveillance is largely a field service activity. Over and above the head office technical staff, an appropriate number of regional inspection offices are required for effective and efficient market surveillance close to markets.

Other areas to consider in the organizational structure, especially if the regulatory authority is an independent organization, include support functions, such as human resources, finance, transportation, and others.

***Existing information/reporting/monitoring***

- Approved organizational structure
- Ministry decisions
- Ministerial decisions
- Financial system documentation

### 10.3.4 Management and personnel (building block no. 6)

***What is meant***

| | |
|---|---|
| Major | Market surveillance and premarket product approval is primarily a people-based activity operating within a specific technical environment, assuming that testing and certification are conducted by third-party organizations. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the technical regulation fields, including the appointment of inspectors with appropriate knowledge of their legal authority with regard to entry and search. |

***How can it be demonstrated?***

In the first place, the regulatory authority should operate with an organizational structure approved by the ministry or its council. For each of the positions,

the skill set (qualifications, training, and experience) should be clearly and formally stated. Special attention should be given to the training and appointment of inspectors, concerning not only their technical capabilities but also their knowledge about their legal authority with regard to entry and search. The ratio between technical and administrative staff is a good indicator of efficacy, with a good guideline being that administrative staff make up no more than 20 percent of the total.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the regulatory authority cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

#### *Existing information/reporting/monitoring*

- Approved organizational structure
- Training records of staff
- Appointment and withdrawal records of inspector certificates
- Actual staffing levels
- Staff turnover figures

### 10.3.5 Premises (building block no. 7)

#### *What is meant*

| | |
|---|---|
| Fundamental | Technical regulation implementation is partly a technical endeavor, but mostly of an administrative nature. Appropriate accommodation for head office staff and technical activities has to be provided, as well as appropriate accommodation in regional offices for inspectors and their equipment. Confidentiality of the information also has to be safeguarded. |

#### *How can it be demonstrated?*

If the regulatory authority is involved in testing and certification, then the concomitant premises for a laboratory or certification body have to be provided (see sections 6, 7, and 8 on "Inspection," "Testing," and "Product Certification," respectively).

Appropriate office space for staff needs to be provided, as well as a few meeting rooms for individual customer discussions to safeguard information lying around on desks and in work spaces. In regional or border control offices, appropriate office space, as well as space for operating or storing inspection equipment are required.

#### *Existing information/reporting/monitoring*

- Consideration of the regulatory authority premises in relation to design, environmental controls, access, and maintenance
- Review of laboratories and environmental controls
- Review of office space and meeting rooms
- Technical requirements as advised by experts in specific technical regulation fields

### 10.3.6 Equipment (building block no. 8)

***What is meant***

| | |
|---|---|
| Fundamental | A wide range of equipment is necessary as denoted by the technical regulation to be inspected and, if relevant, tested and certified. Inspection offices should be issued with appropriate inspection equipment. Working standards should be maintained against which inspection equipment can be calibrated continuously. Working standards must be traceably calibrated to national measurement standards at predetermined intervals. |

***How can it be demonstrated?***

Equipment used in the test laboratories of the regulatory authority should comply with good laboratory practices. (See sections 7 and 8 on "Testing" and "Product Certification," respectively, for further details and diagnostics.) The equipment necessary to inspect products covers a vast range of instruments. Expert advice is required to evaluate the range of instruments and their respective accuracy classes properly.

The accuracy of the regulatory authority's equipment should be above reproach to ensure that any challenge, legal or otherwise, can be dealt with. Hence, it is good practice to keep working standards against which inspection equipment can be calibrated. The working standards must be calibrated traceably to the national measurement standards at defined intervals. The inspection equipment used by inspectors in the field should be calibrated frequently against the working standards.

***Existing information/reporting/monitoring***

- Consideration of the technical regulation fields of activity
- Demonstrable equipment needs of the regulatory authority
- Review of working standards
- Review of inspection equipment
- Review of maintenance measures for all measuring equipment

### 10.3.7 Quality system documentation (building block no. 9)

***What is meant***

| | |
|---|---|
| Major | It is good practice for the regulatory authority to operate in accordance with a formal quality management system. This includes compliance with ISO/IEC 17025 regarding laboratory services, ISO/IEC 17065 for product certification, and ISO/IEC 17020 for inspection activities. |

***How can it be demonstrated?***

The laboratories of the regulatory authority should comply with the requirements of ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"); it would even be appropriate to have been accredited. The same applies for relevant product certification activities that should comply with ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services"). See sections 7 and 8 on "Testing" and "Product Certification," respectively, for details.

As for its inspection activities, it is good practice to comply with ISO/IEC 17020 ("Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection"). Accreditation of inspection activities

will independently demonstrate the competency of the regulatory authority, thereby enhancing its standing among stakeholders, and will support the authority in legal disputes.

For all of these, quality system documentation is required. It should be developed in three levels: policies, general procedures, and work instructions or standard operating procedures. Appropriate records are an important element of the quality management system. It is especially the premarket approval records and inspection records that are important as legal documents indicating an effective implementation of the technical regulation legislation. The more modern approach would base these on a proper information and communication technology (ICT) system.

***Existing information/reporting/monitoring***

- Consideration of the regulatory authority's formal quality management system and its compliance with relevant standards, such as ISO/IEC 17020, ISO/IEC 17025, and ISO/IEC 17065

## 10.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

### 10.4.1 Benchmark and significance

The development and implementation of a technical regulation must comply with the requirements of the WTO TBT Agreement if the country is a WTO member. Furthermore, if a technical regulation framework has been promulgated (see section 10.2.2), the process has to follow the framework's guidelines as well. Good regulatory practices include

- A requirement that the technical regulation be based on international standards, where these exist and are appropriate;
- Notification of draft technical regulations to the WTO TBT Secretariat 60 days before they are promulgated;
- Conformity assessment procedures that facilitate mutual recognition among WTO members; and
- Granting of transition periods for implementation

The preventive component of trade-related technical regulation consists of premarket approval of high-risk products. This could be product type approval, consignment inspection, compliance of the supplier with a defined quality management system, or any combination of these, as relevant. The organizations responsible for these must be clearly identified. They could be technically competent third-party conformity assessment service providers that conduct the testing and certification, or they could include the regulatory authority conducting consignment inspections before products are released for the market. The combinations will be determined by the technical regulation requirements.

Market surveillance is the repressive part of technical regulation implementation. Registered inspectors with appropriate entry and search authority inspect market activities as they relate to technical regulation legislation or regulations. Upon uncovering noncompliant products, the inspectors, in coordination with

the director, institute sanctions and legal proceedings against the relevant suppliers.

In a modern economy, the regulatory authority needs to demonstrate its integrity and technical competency in order to engender trust among all stakeholders. It is therefore good practice if the regulatory authority is accredited to ISO/IEC 17020 for its inspection activities; to ISO/IEC 17025 for its testing work; and to ISO/IEC 17065 if it is involved in product certification, for its laboratory as well as on-site work.

### 10.4.2 Developing technical regulations (building block no. 10)

***What is meant***

| | |
|---|---|
| Fundamental | The development of a technical regulation is initiated by the state or its competent authorities once a market failure is identified. Before embarking on the development of a technical regulation, the responsible ministry should initiate a regulatory impact assessment. |
| Fundamental | The WTO TBT Agreement requires the technical regulation to be based on an international standard, if available and suitable. |
| Fundamental | Draft technical regulations must be notified to the WTO TBT Secretariat 60 days before its promulgation. |

***How can it be demonstrated?***

**Regulatory impact assessment**. Once the state indicates that it wishes to deal with a market failure by developing and implementing a technical regulation, it should initiate a regulatory impact assessment (RIA) to determine the severity of the problem, identify various options for dealing with the problem, determine the socioeconomic advantages and disadvantages of the various options, and consider whether the infrastructure to implement the technical regulation is available in the country or whether it will have to be developed. The RIA should provide the authorities with the necessary information to make an educated decision.

**Referencing standards**. The WTO TBT Agreement requires that the technical regulation be based on an international standard, should a relevant one exist. Such a standard could also be an international standard adopted as a national standard. Replicating the text of the standard in the actual technical regulation is no longer seen as good practice because updating it presents challenges as technology develops. A better practice is to reference standards either directly or indirectly. Some economies prefer direct referencing; others, like the European Union (EU), use indirect referencing, depending on the juridical system and political preferences. For a detailed description of the referencing possibilities, see module 7, section 7.4, of the QI Toolkit.

**Notification to the WTO**. All draft technical regulations falling within the scope of the WTO TBT Agreement, whichever ministry or authority develops them, must be notified to the WTO TBT Secretariat if the country is a WTO Member 60 days before the regulation is to be promulgated. This is to give other WTO members the chance to comment. All comments received have to be considered without favoring any particular country. Once the technical regulation is promulgated, a transition period for its implementation should be agreed upon by stakeholders. The WTO suggests six months.

**National consultation process**. Good regulatory practice suggests that technical regulations should be developed in an open and transparent manner. If a regulation is based on a national or international standard, then a large part of the technical regulation is already subject to a public consultation process. The RIA can also be seen as part of the national consultation process. Progressive jurisdictions publish draft technical regulations for public comment, and if the socioeconomic impact is immense, public hearings are also held. All of this presupposes that there is time for public comment; some technical regulations have to be implemented immediately to deal with a crisis, in which case such consultations are of secondary importance.

#### *Existing information/reporting/monitoring*

- Relevant technical regulation legislation
- Records of RIAs conducted
- Records of all the ministries regarding the development of technical regulations
- Notification records of the WTO TBT Secretariat
- Published implementation transition periods

### 10.4.3 Premarket approvals (building block no. 11)

#### *What is meant*

| | |
|---|---|
| Fundamental | For selected high-risk products, the regulatory authority implements a consignment inspection regime to ensure that products meet technical regulation requirements before they are released to the market. |

#### *How can it be demonstrated?*

Certain high-risk products may have such a deleterious effect on people, fauna and flora, and the environment that the technical regulation requires each consignment to be inspected and released before marketing. These products would typically include certain types of processed food, such as canned fish. The regulatory authority would inspect and sample each consignment of such products to determine whether the products meet stated requirements.

The regulatory authority may conduct the inspection, testing, and certification, or it could designate third-party inspection bodies to do so. The latter would typically operate in the country of origin of the imported products to ensure that only compliant products are shipped. The regulatory authority will typically inspect consignments on home soil—namely, at all the ports of entry, at the premises of manufacturers or producers, and in local warehouses. The testing and certification could be conducted by accredited and designated test laboratories if the regulatory authority does not do so.

Establishing the testing and certification capacity for all products that are subject to technical regulations requires immense resources. Hence, low- and middle-income countries will frequently have to rely on testing and certification evidence from the exporting countries for products that are imported. The regulatory authority has the responsibility in this case to evaluate such inspection and test certificates offered by the importers or suppliers to ascertain whether they (a) relate to the products under consideration, (b) provide evidence of compliance with the local technical regulation, and (c) are likely to be fraudulent.

The inspection and sampling plans of such products have to be formalized, taking into consideration the risks associated with products that do not comply with stated requirements. These procedures should be publicly available. Inspection and testing of perishable goods are a specific challenge regarding the time to market release, as are freight and warehousing charges of consignments awaiting release. Bond stores are often used for warehousing products away from ports of entry or factories to alleviate congestion in such cases.

The regulatory authority must keep complete records of all consignment inspections in a way that precludes tampering and such that they can easily be retrieved as required. The record-keeping system must be able to withstand the scrutiny of a court of law.

***Existing information/reporting/monitoring***

- Relevant technical regulation legislation
- Formal consignment inspection procedures of the regulatory authority
- Consignment inspection records of the regulatory authority

### 10.4.4 Market surveillance (building block no. 12)

***What is meant***

| | |
|---|---|
| Fundamental | The regulatory authority must provide for the market surveillance of all products falling within the scope of the technical regulations for which it is responsible and use risk assessments to prioritize their activities. |

***How can it be demonstrated?***

Market surveillance is an audit activity whereby a regulatory authority monitors the compliance of products in the marketplace with technical regulations. It is a combination of inspection and testing of a select number of products; it is not the certification thereof. The supplier is responsible for the routine compliance testing and certification of the product; market surveillance determines whether the supplier has complied with its responsibilities.

Without market surveillance and the imposition of sanctions, technical regulation fails as some suppliers eventually cut corners with noncompliant products. On the other hand, market surveillance cannot cover all the products falling within the scope of technical regulations; it is logistically not feasible. Therefore, regulatory authorities have to rely on inspecting selected products or suppliers; that is, it becomes an audit function. (For further details, see module 7, section 7.7, of the QI Toolkit.)

In planning market surveillance, the regulatory authority should follow the principles of proportionality; that is, the action taken should be in accordance with the level of risk or nonconformity, and the influence upon the economic entity should not be more than necessary for performing the task of market surveillance. Market surveillance can be either planned or off-schedule, depending on the ongoing nature of the activity or for dealing with an immediate threat or at the request of a court of law.

***Existing information/reporting/monitoring***

- Working plans of the regulatory authority
- Risk assessment methodology used by the regulatory authority
- Market surveillance records

### 10.4.5 Sanctions (building block no. 13)

***What is meant***

| | |
|---|---|
| Fundamental | The regulatory authority must implement administrative sanctions to remove nonconforming products from the marketplace and institute legal proceedings against suppliers if they fail to heed administrative sanctions. |

***How can it be demonstrated?***

When nonconforming products are uncovered in the marketplace, the sanctions take two forms: administrative sanctions and legal proceedings. Administrative sanctions are imposed by the regulatory authority on the supplier of nonconforming products with the aim of removing such products from the marketplace. The administrative sanctions, as provided for in technical regulation legislation, should include a cessation of all marketing in all cases. Thereafter, depending on the severity of the nonconformance, products may have to be recalled and reworked, destroyed, or reexported (in the case of imported products), depending on circumstances and the nature of the nonconformance.

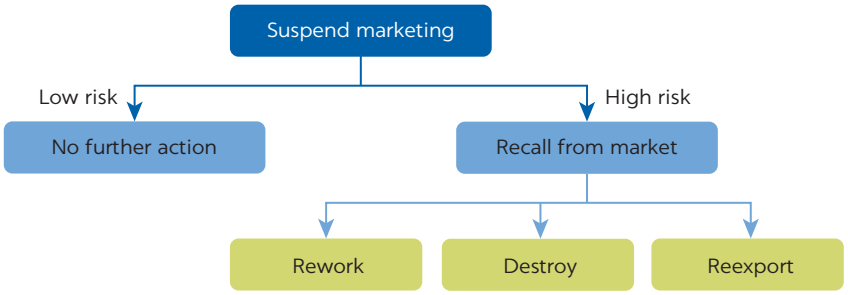
These sanctions take the form of a formal order issued to the supplier of the products. Once the supplier has complied with the order, all further sanctions cease. Administrative sanctions are depicted graphically in figure 10.2.

Should the supplier fail to heed the order, then the regulatory authority initiates legal proceedings through the courts to get the supplier to deal with the issue. The court may order the confiscation of offending products by the state or impose fines or even jail sentences, depending on the severity of the issue and the judicial custom and practice of the country. The regulatory authority should not be given the mandate to impose fines, because this only opens the door for corrupt practices.

***Existing information/reporting/monitoring***

- Market surveillance planning documents
- Market surveillance records
- Records of sanctions instituted
- Records of relevant court proceedings

FIGURE 10.2
**Typical administrative sanctions against noncompliant products**



### 10.4.6 Training system (building block no. 14)

***What is meant***

| | |
|---|---|
| Major | Trained and skilled inspectors are a vital component of an effective and efficient market surveillance system. |
| Major | Over and above their technical background, inspectors should also be trained in the authority and responsibilities they have in a legal sense. They should be appointed and issued with an inspector's identification, and this should be withdrawn if the inspector leaves the service. |

***How can it be demonstrated?***

(*Note:* Technical staff working in laboratories are discussed in sections 7 and 8 on "Testing" and "Product Certification," respectively.)

High demands are placed on appropriately educated, trained, and experienced inspectors and technical staff. Inspectors should have the necessary technical background for the specific products they will be involved in, as well as a proper grounding in risk analysis and inspection techniques.

Inspectors are generally empowered by legislation to enter and search premises and vehicles without a search warrant, where products that fall within the scope of technical regulations are suspected to be marketed. To ensure that they operate professionally and in compliance with the law, inspectors must be trained in the legal aspects of their work. Thereafter, they are officially appointed as inspectors and issued a card identifying them as such. This identification card should be shown to the responsible persons when entering premises or vehicles for inspection. The identification card must be withdrawn once the inspector is no longer involved in inspections.

The regulatory authority must therefore provide for the training of its own staff—a requirement that increases with the development of the technical regulation regime into a much more preventive one as it is reengineered as a regulatory management system. Initial training programs can be initiated by technical development programs, but eventually they have to be internalized and provided by the regulatory authorities, possibly in collaboration with tertiary technical education institutions.

***Existing information/reporting/monitoring***

- Training programs
- Training records
- Appointment records of inspectors
- Records of inspectors' identity cards issued and withdrawn

## 10.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

### 10.5.1 Benchmark and significance

An international recognition mechanism for a technical regulation regime does not exist. However, if the country is a member of the WTO, all its obligations in relation to the WTO TBT Agreement must be fulfilled. These include the notification of the modalities of the technical regulation regime, development of technical regulations, and the establishment of a national WTO TBT Inquiry Point, among others. A specific ministry, usually the ministry responsible for trade and industry, should be designated by the government to take responsibility for this compliance.

### 10.5.2 Liaison with regional organizations (building block no. 15)

***What is meant***

| | |
|---|---|
| Major | If the country is a member of a regional construct, then it may be that technical regulation is being harmonized across the region through protocols, regional legislation, or similar arrangements. This means the country must participate in the relevant technical forums at the regional level. |

***How can it be demonstrated?***

One of the necessities of a regional common market is the harmonization of technical regulations across all member states to facilitate the free movement of goods throughout the region. Various mechanisms to develop and foster such harmonization are used, such as the following:

- Promulgation of regional technical regulations that all member states must implement
- Regional harmonization of standards, metrology, accreditation, and conformity assessment modalities to support technical regulations
- Regional recognition of technical regulation premarket approvals
- Regional recognition agreements on product certification and so on

Member states of such regional common markets should participate actively in relevant regional technical regulation forums where such issues are discussed and agreed upon for implementation across the region.

***Existing information/reporting/monitoring***

- Membership of regional common markets
- Regional TBT protocols, agreements, or similar arrangements
- Regional common market technical regulation forums
- Reports of attendance at regional technical regulation discussions

### 10.5.3 Liaison with international organizations (building block no. 16)

***What is meant***

| | |
|---|---|
| Fundamental | If the country is a member of the WTO, then it must comply fully with the requirements of the WTO TBT Agreement regarding notifications and information about standards, conformity assessment, and technical regulations. |
| Fundamental | The WTO member must designate the notification authority responsible for the notifications and convey this information with contact details to the WTO TBT Secretariat. |

***How can it be demonstrated?***

The WTO TBT Agreement places a number of obligations on WTO member states regarding notifications and information (table 10.2).

***Existing information/reporting/monitoring***

- Notification authority records
- WTO TBT Agreement records of notifications

**TABLE 10.2 WTO TBT Agreement notification responsibilities**

| ITEM | REFERENCE | TYPE OF MEASURE | PERIODICITY |
|---|---|---|---|
| *I* | *Statements on implementation and administration of the WTO TBT Agreement* | | |
| a | Article 15.2 | Administrative arrangements, laws or regulations, measures in existence or taken to ensure the implementation and administration of the TBT Agreement | Upon entry into force of the WTO Agreement<br>When revised or updated |
| *II* | *Notifications of proposed and adopted technical regulations or conformity assessment procedures by central and local governments* | | |
| a | Article 2.9 | Technical regulations | Ad hoc |
| b | Article 2.10 | Technical regulations (urgent) | Ad hoc |
| c | Article 3.2 | Technical regulations (local government) | Ad hoc |
| d | Article 5.6 | Conformity assessment procedures | Ad hoc |
| e | Article 5.7 | Conformity assessment procedures (urgent) | Ad hoc |
| f | Article 7.2 | Conformity assessment procedures (local government) | Ad hoc |
| *III* | *Notification of bilateral or multilateral agreements (Article 10.7)* | | |
| a | Article 10.7 | Bilateral or multilateral agreements on technical regulations, standards, and conformity assessment procedures | Ad hoc |
| *IV* | *Notification under paragraphs C and J of the Code of Good Practice on the Preparation, Adoption, and Application of Standards (Annex 3 to the Agreement)* | | |
| a | Annex 3, paragraph C | Acceptance of or withdrawal from the *Code of Good Practice for the Preparation, Adoption and Application of Standards* | Once originally<br>When status changes |
| b | Annex 3, paragraph J | Work programs on standardization activities | Biannually |

*Source:* WTO 1995.
*Note:* TBT Agreement = Agreement on Technical Barriers to Trade; WTO = World Trade Organization.

## NOTE

1. The WTO TBT Inquiry Point is an official or office in a WTO-member government designated to deal with inquiries from other WTO members and the public on technical barriers to trade.

## STANDARDS REFERENCED IN SECTION 10

ISO and IEC (International Organization for Standardization and International Electrotechnical Commission). 2012. "ISO/IEC 17020: Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." 2nd ed. Ref. no. ISO/IEC 17020:2012(E), ISO, Geneva.

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## REFERENCE

WTO (World Trade Organization). 1995. "Agreement on Technical Barriers to Trade." Treaty document, WTO, Geneva.