7

Technical Regulation

7.1 THE TECHNICAL REGULATION SPECTRUM AND DEFINITIONS

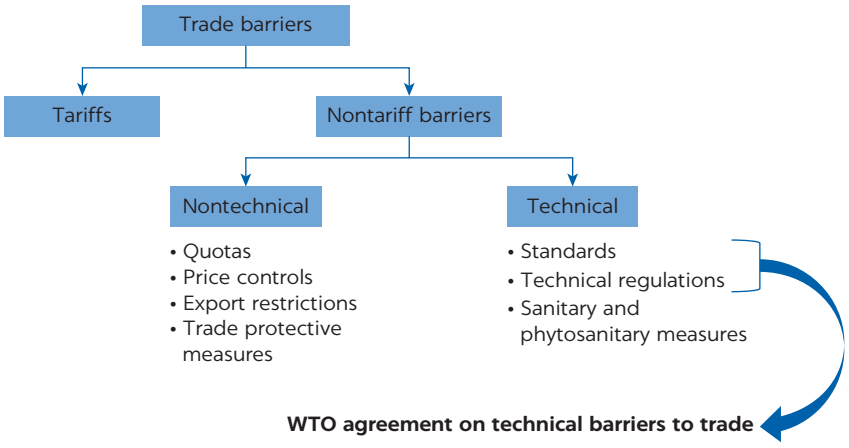
Products in the market could fail and become hazards for the people or the environment. The reasons are manifold: they may not comply with relevant standards, manufacturers might have skimped on manufacturing controls, suppliers may just take a chance to see whether they can get away with substandard products, and so on. Consumers generally cannot distinguish between products that may fail and those that will not. Hence governments have taken the responsibility to establish controls over products in the marketplace that would limit such failures in order to protect their citizens and the environment. These mechanisms have been, and still are, known by different names in many countries, but they are now collectively understood as technical regulations at the international level.

In the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), a technical regulation is defined as a "document which lays down product characteristics or their related processes and production methods, including applicable administrative provisions, with which compliance is mandatory" (WTO 1994, annex 1). Technical regulations are therefore legally binding prescriptions and must be applied by all economic operators in a given market, irrespective of their size or where they come from.

Technical regulations have been around for centuries. They are, in essence, barriers to trade. With the development of global trade, some differences in technical regulations across trading partners were being highlighted as *unnecessary* barriers to trade, and the first efforts to harmonize technical regulations at the international level were incorporated into the General Agreement on Tariffs and Trade (GATT). These were reviewed and refined for the various agreements underpinning the Marrakesh Agreement, which was signed in 1994. The Marrakesh Agreement provided for the establishment of the WTO, which came into being in 1995.

The WTO distinguishes between tariff barriers and nontariff barriers (figure 7.1). Of the various nontariff barriers, standards and technical regulations are dealt with in the TBT Agreement. Sanitary and phytosanitary (SPS) measures—the companion to technical regulations—are dealt with in

FIGURE 7.1
Categories of barriers to trade



Note: WTO = World Trade Organization.

another agreement: the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). The two agreements are mutually exclusive by definition, as discussed further in section 7.10.

The WTO TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are nondiscriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety or of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment.

Five principles underpin the WTO TBT Agreement:

- The same treatment has to be accorded to imports from all WTO member states.
- Imported and domestic products should be treated the same.
- Standards, conformity assessment procedures, and technical regulations should not be disguised trade barriers.
- Technical regulations should achieve their objectives by means that minimize restrictions on trade.
- Draft standards and technical regulations should be published in a timely manner to enable other WTO member states to comment.

Technical regulations are implemented by governments for many reasons. To limit these to justifiable causes, the WTO TBT Agreement provides guidance on which policy objectives are considered legitimate, namely, that no country should be prevented from taking measures necessary to ensure (a) national security; (b) the protection of human, animal, or plant life or health; (c) the protection of the environment; or (d) the prevention of deceptive practices. These, however, should not be applied in a manner that would constitute either a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade (WTO 1994, Article 2.2).

7.2 DIFFERENCES BETWEEN STANDARDS AND TECHNICAL REGULATIONS

There are similarities between standards and technical regulations, but there are also some major differences. Technical regulations should be implemented only for legitimate reasons, whereas standards go beyond that. Technical regulations are used by the state to regulate and control products that may be deleterious to the health and safety of the population, fauna, flora, and the environment, whereas standards are used by all parties to provide for a common understanding and implementation of requirements for products and services by agreement or contract. Other differences relate to their legal status, the responsibilities for development, and implementation, rather than the technical details of the products dealt with (Inklaar 2009).

7.2.1 The state and its authorities

Technical regulations are part of the body of legislation of a country or a region. The responsibility for the development and promulgation of technical regulations lies with the state and its competent authorities. In developing technical regulations, the transparency provisions of the WTO TBT Agreement must be honored. The enforcement of technical regulations, too, is the sole responsibility of the state and its competent authorities. For this reason, technical regulations include administrative provisions, which are generally absent from standards.

Standards, on the other hand, are developed and published by public or private standards bodies and principally in accordance with internationally recognized principles such as transparency, openness, and consensus (see module 3: Standards, section 3.4, on good standardization practice). The governance structures of the bodies responsible for the approval of standards may include representatives from the state in the case of public standards bodies. Standards are also considered voluntary; that is, implementation is by choice of the user.

The state may decide to delegate certain tasks in connection with the development of technical regulations to "nonauthorities." For example, the state may subcontract the regulatory impact assessment (RIA) to an organization specializing in such assessments. Or market surveillance may be delegated to a private inspection body. It is good practice to base the technical regulation on a standard; hence the state may request the national standards body to develop the national standard that will be referenced in the technical regulation. But the state or its competent authority must remain in control of the regulatory process at all times. It cannot delegate its legislative competency and accountability to "unauthorized" parties that do not have the relevant constitutional legitimacy.

Other than the provisions in the WTO TBT Agreement regarding the development of technical regulations, the way in which the state fulfills its regulatory responsibilities and tasks is not prescribed in any binding regional or international instruments. There are, however, tried and tested international good practices that should be considered (as discussed below in section 7.9).

7.2.2 Users and affected parties

Standards are recommendations. Interested parties or organizations apply them on a voluntary basis. These users decide for themselves which standards

are relevant and whether the benefits warrant the cost of implementation. Standards can be part of a contractual obligation, or they can be implemented on the strength of market perceptions. Noncompliance may certainly limit market opportunities, result in relinquishing a lucrative contract, or impose civil-law consequences for noncompliance, but noncompliance is not an offense by itself, punishable by the state.

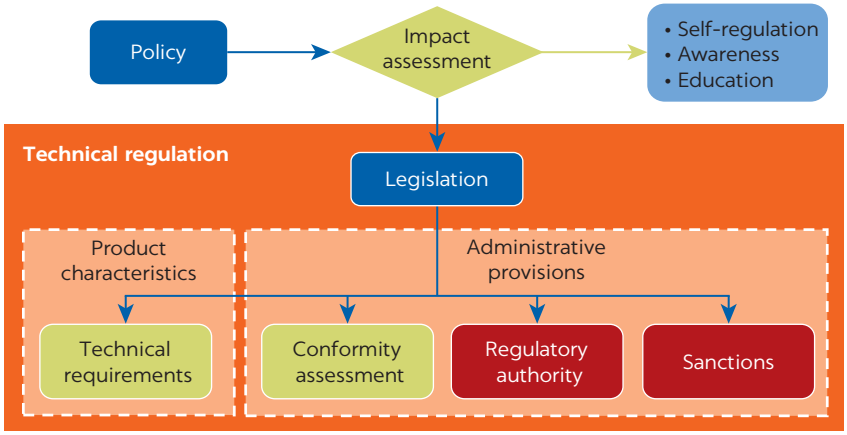
In contrast, technical regulations are legally binding prescriptions. They must be complied with by all parties in the market, whether big or small, local or foreign, and regardless of the costs of implementation. Noncompliance is an offense punishable by law. This may become an existential threat for small and medium enterprises (SMEs) if compliance is technically challenging or expensive. Technical regulations are sometimes also a hindrance to innovation because of their prescriptive nature. This may damage the competitiveness of industry because a technical regulation has to be complied with in its totality.

Standards that are badly written, difficult to understand, or ambiguous are seldom used and ultimately are forgotten. Technical regulations that are difficult to understand or even ambiguous must nevertheless be complied with. This places a responsibility on the state to ensure that technical regulations are clear, stated in simple language, and use performance criteria rather than design or prescriptive characteristics (WTO 1994, Article 2.8).

7.3 ELEMENTS OF A TECHNICAL REGULATION SYSTEM

An international binding standard for the development and implementation of a technical regulation does not exist. Technical regulations are developed in accordance with the customs and practices of countries or in accordance with state prescriptions regarding national legislation. A type of building-block approach for technical regulations (figure 7.2) has emerged over the past two decades that helps tremendously in understanding the various approaches practiced by countries regarding technical regulation content. Anecdotal evidence suggests that if any of the building blocks are not properly provided for in the technical regulation, then the regulation may prove to be ineffective.

FIGURE 7.2
Building blocks of a technical regulation



Source: Adapted from Racine 2011.

Some governments endeavoring to implement regulatory management (see section 7.9) have defined the development steps, structure, and implementation modalities—the building blocks—of technical regulations for their countries. These are generally known as a technical regulation framework and are given legal certainty through an appropriate legislative instrument. This is necessary because the technical regulation framework has to be implemented by all regulatory authorities at the national, provincial, or local levels. Such a framework is the most effective manner for ensuring the compliance of all the regulatory authorities with the country's obligations in relation to the WTO TBT Agreement or similar regional arrangements.

A technical regulation is initiated through an intention (for example, contained in a policy statement) by the government to deal with a specific market failure and to ensure a legitimate objective. Before a technical regulation is contemplated, an RIA should be conducted to determine how big the problem is, what the socioeconomic costs and benefits are, and whether the infrastructure to implement the technical regulation exists in the country.

If the decision is to develop and implement a technical regulation, then it should contain a description of the following:

- *Technical requirements.* These should be based on international standards (or their national adoption), and they can either be included in the text of the technical regulation (no longer seen as good practice) or referenced. Referencing standards in technical regulation is good practice, and a number of possibilities for doing so are available (as discussed in section 7.4).
- *Conformity assessment.* This would be any combination of inspection, testing, and certification, either by the supplier (that is, a supplier's declaration of conformity [SDoC]) or by independent third parties whose competency is demonstrated by accreditation and who are acceptable to the regulatory authority (that is, designated organizations).
- *Regulatory authority.* The regulatory authority is primarily responsible for in-market surveillance (which may include manufacturers' premises and warehouses) to ensure all suppliers' continued compliance of products with the technical regulation. For very high-risk products, premarket approvals may be required as well. The regulatory authority has to initiate sanctions if suppliers do not meet requirements.
- *Sanctions.* The regulatory authority applies administrative sanctions such as directives for the recall and destruction of noncompliant products. If suppliers do not heed administrative sanctions, then courts of law should get involved. Regulatory authorities should not be given the mandate to impose fines; that only invites corrupt practices. Fines are best reserved for courts of law.

7.4 THE ROLE OF STANDARDS AND WAYS TO REFERENCE THEM

The WTO TBT Agreement clearly requires that technical regulations be based on international standards where these exist or where their completion is imminent, except where such standards would be ineffective or inappropriate—for example, because of fundamental climatic or geographical factors or fundamental technological problems. The TBT Agreement does not identify the organizations it considers to be international

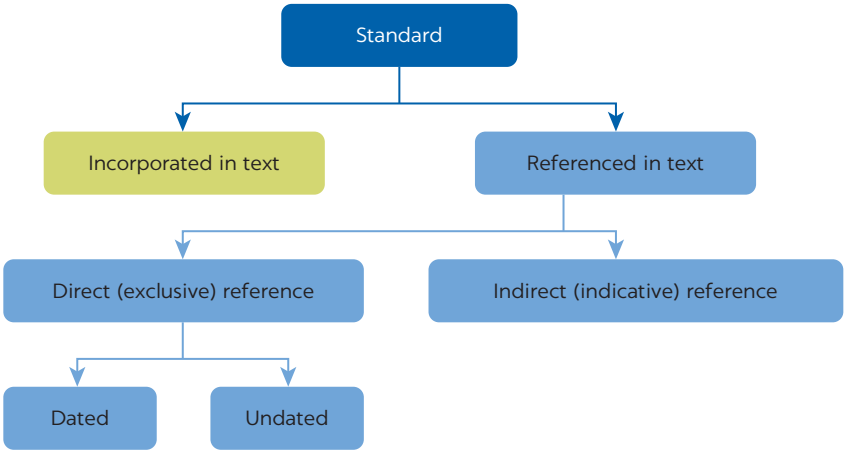
standards developers by name; nor does it provide a list of international standards. The WTO's Committee on Technical Barriers to Trade therefore published a decision in 2000 (WTO 2000) on the principles to be used for deciding whether a standard is an international standard (as discussed in module 3: Standards, section 3.4, on good standardization practice) rather than naming specific international standards bodies, as does the WTO SPS Agreement.[1]

Over and above the requirements of the WTO TBT Agreement, the use of standards for defining the technical requirements of a technical regulation also holds some important advantages:

- The legislator can rely on recognized solutions and does not need to reinvent the wheel.
- The methodology of developing standards—including principles such as consensus, openness, and transparency—more readily facilitates the acceptance of the technical regulation.
- Standards can be more readily updated if and when technology or circumstances change.
- The overall development process is more efficient (for example, avoiding costly duplication of effort), and the costs of developing the technical requirements are largely shifted from the public to the private sector.
- To the extent that many sources of expertise are involved in standards development, and that the final outcome must receive support from interested parties to be accepted, standards may better reflect technical reality in the market than do technical regulations developed in isolation.

A few possibilities present themselves for using international standards as the basis for technical regulations. These include incorporation of the standards text in the technical regulation itself, various ways of direct (exclusive) referencing of standards, and indirect (indicative) referencing of standards (figure 7.3). Obviously, national or regional standards that are adoptions of international standards would also qualify as a means of meeting the WTO TBT Agreement requirements.

FIGURE 7.3
Use of standards in technical regulations



7.4.1 Incorporation of the text

Incorporation of the text of the standard into the text of the technical regulation is the time-honored way of using the standard. Many legislators would prefer this methodology because it is straightforward and legally sound.

However, it comes with some serious disadvantages:

- The technical regulation can quickly be rendered out-of-date, especially in fast-developing technologies. It is a truism that once on the statute books, it is unlikely that legislation (and a technical regulation is part of legislation) is reviewed continuously and consistently. Technologically outdated technical regulations are problematic because they still have to be complied with, and imported products manufactured in accordance with updated international standards are technically frozen out of the market. It is an even bigger challenge for local industries that then can no longer export their products if complying only with national technical regulation.
- Many standards reference other standards, and if this approach is followed to its logical conclusion, all of these will also have to be incorporated into the technical regulation. This becomes a complicated and inefficient way of dealing with technical requirements.
- There are known instances in which the text of the standards has been copied inaccurately in technical regulations, resulting in challenges to implement irrational requirements at best and impossible requirements at worst.

Including the text in the technical regulation does have the advantage that only relevant parts of the standard having a direct bearing on safety and health issues, for example, can be selected. For this reason, some jurisdictions still favor this approach above referencing the complete standard, which may include requirements not considered relevant for regulation.

However, given the disadvantages, incorporating the full text of a standard in the technical regulation has fallen out of favor in many jurisdictions, and preference is given to referencing standards instead.

7.4.2 Referencing standards

Referencing standards is a good regulatory practice to describe the technical requirements of the technical regulation. There are a few possibilities for this approach, all of which are being used in various jurisdictions. Each has its own advantages and challenges. The two main groups are direct and indirect referencing.

Direct (exclusive) referencing

In direct, or exclusive, referencing, the standard is referenced by at least the number and the title. An abstract is sometimes included, but this is not absolutely necessary as long as the number and title identify the standard unambiguously. The demonstration of compliance with the technical regulation is, in this case, always in accordance with the referenced standard.

The exclusive reference may be dated or not. If the reference to the standard includes its date of publication, then only this version can be used for compliance purposes. The regulatory authority remains the "master of the procedure" because any revision of the standard does not automatically lead to the revision of the technical regulation. The regulatory authority has to update the reference

to the revised standard for the technical regulation to be updated. Although some legislators may prefer this situation, it also places responsibility on the regulatory authority to keep track of developments regarding the revisions of the referenced standards. If only certain parts of the standard are required for regulatory purposes, dating the reference would be the only way to do it.

If the exclusive reference is not dated, then the technical regulation is updated automatically if and when the standard is revised; that is, it will always be the current version of the standard that is cited when contemplating compliance. This is an elegant way to keep the technical regulation updated for fast-moving technologies. The challenge of this methodology is that the regulatory authority is no longer the sole "master of the procedure"; some of the regulatory authority's jurisdiction has been relinquished in favor of the standards body. Whether this is a real issue is a risk the regulatory authority has to consider before adopting this methodology.

Indirect (indicative) referencing

In indirect, or indicative, referencing, the relevant standard is not defined in the technical regulation by number and title. The technical regulation provides for essential requirements that have to be complied with in an indicative way. The relevant standards are then published in a separate official journal. Compliance with these standards confers compliance of the product with the technical regulation's essential requirements. The list of standards can obviously be either dated or undated.

The European Union (EU) New Approach directives are probably the best-known exponents of this system, and in their case, the standards—EN harmonized standards—remain "voluntary."[2] A further element of the EU system is that suppliers can in theory also use standards other than the EN harmonized standards, but then the burden of proof that these other standards also fulfill the essential requirements of the New Approach directives is shifted to the supplier. In practice, therefore, it is debatable whether any supplier would go this route, because it is much less of a hassle to use the EN harmonized standards.

Choice of referencing system

The choice as to which system should be used depends on the customs and practice of the country and on the relationship between the regulatory authorities and the national standards body. If a good understanding is in place, then using undated references is a useful mechanism to keep technical regulations up-to-date. The regulatory authority then also does not have the challenge of putting a resource-intensive maintenance system in place. If there is not a good working relationship between the regulatory authorities and the national standards body, dated references may be the better option, but the regulatory authority then has to establish a proper maintenance system to keep the references up-to-date. Whatever the choice, it should be applied consistently across all regulatory authorities and should be part of the formal technical regulation framework (see section 7.9.3).

Anecdotal evidence suggests that for the indicative referencing to work well, a good product liability regime has to be in place, especially if standards other than those on the official list are used by suppliers. The regulatory authority must be given additional muscle to deal with products that do not comply with the listed standards but with standards chosen by the supplier that are still considered noncompliant with the technical regulation by the

regulatory authority. If such a product liability system is not in place, then direct referencing would be the better approach, even though it is more restrictive regarding standards that may be used by the supplier.

7.5 CONFORMITY ASSESSMENT MODALITY GOOD PRACTICES

In all technical regulation regimes, compliance evidence (for example, inspection, testing, or certification) in some shape or form is required by the regulatory authorities to assess whether products falling within the scope of technical regulations actually comply with their technical requirements. The conformity assessment requirements should be defined in the technical regulation. Such evidence can be provided by the supplier (the first party) or by an entity independent from the supplier (the third party). In the case of technical regulations, the purchaser, consumer, or user (the second party) is not directly involved in demonstrating compliance of the product with stated requirements.

7.5.1 Supplier's Declaration of Conformity (SDoC)

A declaration by the supplier that the product complies with the requirements of the technical regulation is called the Supplier's Declaration of Conformity (SDoC). Sometimes the expression "self-certification" is used, but this is totally incorrect because "certification" by definition involves a third party. This is so even if the supplier uses the services of an outside laboratory to test the relevant products but issues the declaration of conformity on its own responsibility. The international standards ISO/IEC 17050-1 and 17050-2 (Parts 1 and 2 of "Conformity Assessment—Supplier's Declaration of Conformity") detail the requirements for an SDoC and have been adopted by the EU and many national standards bodies.

An SDoC is considered the most cost-effective approach for suppliers to demonstrate conformity because it does not require third-party inspection, testing, or certification. Additional savings may be realized in costs associated with sales losses because of the time otherwise needed for third-party approvals. The Organisation for Economic Co-operation and Development (OECD) has shown that the use of SDoCs instead of third-party conformity assessment regimes leads to an increase in trade (Flies, Gonzales, and Schonfeld 2008). It therefore does not come as a surprise that major industry groups such as the information technology and automotive industries are advocating the use of SDoCs wherever they can.

An SDoC is acceptable for demonstrating compliance with a technical regulation if the regulation provides for such a mechanism. In general, this will be the case only if the following conditions are in place: (a) the market demands or allows it; (b) the risks associated with noncompliance are relatively low; (c) the penalties for noncompliance are implemented and are effective deterrents; (d) options for efficient recourse in the event of noncompliance exist; and (e) the industry sector to which it applies is highly dynamic, responsible, and has a history of compliance (Flies, Gonzales, and Schonfeld 2008).

SDoCs are acceptable for technical regulations in quite a few instances in high-income economies. Typical examples include toys, personal protective equipment, and recreational craft in the EU; radio and telecommunication

equipment in Australia, Canada, the EU, Japan, New Zealand, and the United States; and motor vehicles and motor vehicle components in Canada, the Republic of Korea, and the United States. SDoCs are not common in low- and middle-income economies, probably because of the lack of proper product liability legislation that would support regulatory authorities in dealing with noncompliant products and the bitter experience of the dumping of unsafe products in the market by unscrupulous traders.

7.5.2 Third-party conformity assessment service providers

If SDoCs are not applicable, because if the technical regulation does not allow for them, then third-party conformity assessment organizations provide inspection, testing, and certification services to demonstrate compliance of the product with technical regulation requirements. Quite a few modalities are possible, as discussed below.

Regulatory authorities

In the past—and this is still the case in many countries—regulatory authorities have the responsibility to inspect, test, and certify products for compliance with technical regulations. This is specifically the case where premarket approvals are required before a product can be legally sold. The ubiquitous use of the national product certification mark (see module 6: Conformity Assessment, section 6.4 on product certification) in many low- and middle-income countries is a typical example of this mechanism. The same applies to the inspection and testing of imported products by the regulatory authorities at the port of entry.

This system is no longer considered good regulatory practice for all types of products. Some of its issues include the following:

- If the regulatory authority's technical competency is suspect, the supplier has nowhere else to go.
- The regulatory authority may choose to reinspect and retest products just to keep its own laboratories occupied.
- Using the national product certification mark for regulatory purposes is arguably an unnecessary barrier to trade and hence is contrary to WTO TBT Agreement principles.
- The regulatory authority is given a license to extract rent in the form of levies that suppliers have to pay irrespective of whether their products are properly inspected and tested.
- The regulatory authority is perceived to take the responsibility for the integrity of the products, whereas that responsibility should remain with the supplier.

Good regulatory practice would indicate that the regulatory authority has the responsibility to conduct market surveillance and impose sanctions in the case of noncompliance. Conformity of the product should be the responsibility of the supplier and the assessment thereof provided by technically competent third-party organizations. Changing from the mandatory application of the national product certification mark to a more modern technical regulation regime is a major challenge for the national standards bodies in many countries because this would affect their income (which is often 80 percent or more dependent on the national product certification mark), over and above the fact that the state may then have to shoulder the additional costs of market surveillance.

Designated organizations

Designation is defined as the governmental authorization of a conformity assessment body to perform specified conformity assessment activities (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). Good regulatory practice would suggest that conformity assessment should be provided by third-party service providers that are technically competent. Technical competency is now generally demonstrated through accreditation by an internationally recognized accreditation body. But before designating a conformity assessment body, the regulatory authority may wish to add requirements not assessed by accreditation.

These requirements could include the ability to take a conformity assessment body to court; for example, it has to be registered in the country, it should be in good standing with other government authorities, it should be up-to-date with tax returns, and so on. In such cases, the regulatory authority would demand evidence additional to the accreditation certificate before it designates the conformity assessment body to provide conformity assessment services for specific technical regulations. The "notified bodies" in the EU are a typical example of such designation.[3]

Designation without accreditation is still being practiced in some countries, but such a system may or may not provide an assurance that the technical competency of the conformity assessment bodies meets minimum requirements, and it is debatable whether it will be accepted by major trading partners, even within the realm of a common market.

Unilateral acceptance

In smaller economies, the regulatory authorities are frequently confronted by a lack of conformity assessment bodies in the country as well as the absence of bilateral or multilateral recognition agreements between their government and the governments of major trading partners. They would then have to resort to the unilateral acceptance of conformity assessment results—at best from accredited conformity assessment bodies abroad, at worst from conformity results provided by suppliers. Either way, the regulatory authority will have little recourse in the case of fraudulent or improper conformity results. The regulatory authority should therefore carefully weigh the risks of accepting such conformity results before accepting them at face value.

Bilateral or multilateral recognition agreements

Trade agreements between countries, either bilateral or multilateral, often include recognition agreements of conformity assessment regimes of the trading partners. These could even be entrenched in treaties and protocols, provided that recourse in the case of incorrect or fraudulent conformity assessment results or noncompliant products is provided for. The recognition of national product certification marks among the common market members is a typical example, as is the recognition of test results from accredited laboratories among major trading partners. These multilateral recognition agreements are difficult to negotiate and take a long time before they start operating.

Other recognition mechanisms are provided for through international systems (see module 6: Conformity Assessment, section 6.9) such as those operated by

- *The International Electrotechnical Commission (IEC)* for electrical and electronic products, such as the IECEE, IECEx, IECQ, and IECRE schemes;[4]

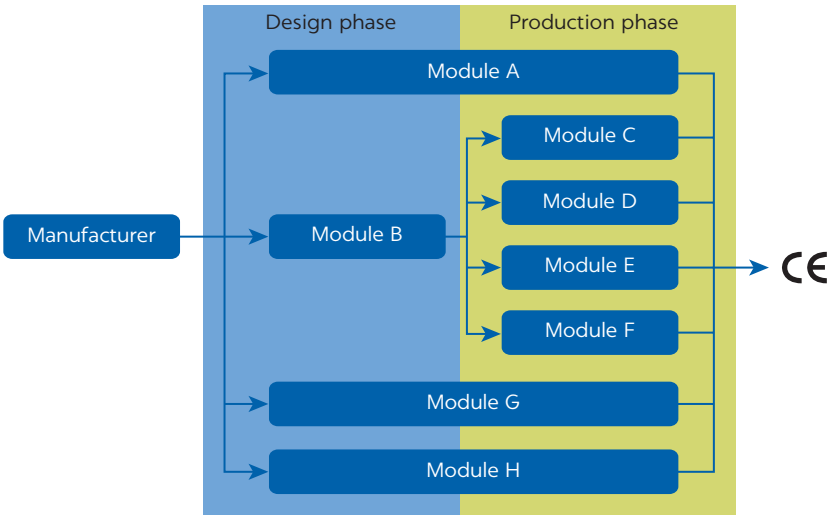
- *The International Organization of Legal Metrology (OIML)* for measuring equipment (Basic Certificate System) and the Mutual Acceptance Arrangement; and
- *The United Nations Economic Commission for Europe (UNECE)* 1958 Agreement for motor vehicle components (see module 6: Conformity Assessment, section 6.9.3).

7.6 REGULATORY AUTHORITY VERSUS SUPPLIER RESPONSIBILITIES

Good regulatory practice indicates that the supplier should at all times remain responsible for the integrity of the product; that is, the supplier must ensure that the product complies with technical regulation requirements. The regulatory authority is responsible for evaluating whether this is the case, but it should never take the responsibility for the integrity of the product, and it should steer clear of actions that could be perceived as such.

Modern technical regulation regimes require the supplier to have all the inspection, testing, and certification conducted to demonstrate the compliance of the product with requirements. These actions should be defined in the technical regulation. A typical example involves the eight modules used in the EU directives (figure 7.4). These modules range from an SDoC for low-risk products (module A) through the involvement of designated test laboratories and certification bodies (the "notified bodies") in increasing levels of involvement (all the other modules), after which the product should receive the

FIGURE 7.4
Simplified chart of EU conformity assessment procedures



Module A: Internal control of production
Module B: EC type examination
Module C: Conformity to type
Module D: Production quality assurance
Module E: Product quality assurance
Module F: Product verification
Module G: Unit verification
Module H: Full quality assurance

Source: EC 2000. ©European Commission. Reproduced with permission from EC, further permission required for reuse.
Note: EU = European Union. The Conformité Européenne (CE) marking is placed on the product and/or packaging by the manufacturer or supplier once all the requirements of the relevant New Approach directive of the EU have been fulfilled.

Conformité Européenne (CE) marking.[5] Another example is the Fastener Quality Act of the United States, which requires that suppliers have their fasteners tested by an accredited laboratory against the requirements of the relevant standard and that the fasteners be marked with a trademark registered with U.S. authorities.

7.7 MARKET SURVEILLANCE, RISK, AND SANCTIONS

Market surveillance is an essential tool for the enforcement of technical regulations. The purpose of market surveillance is to ensure that the products placed on the market comply in all respects with the requirements of the relevant technical regulation to safeguard the health and safety of the country's people, fauna and flora, and the environment. Market surveillance is also important from the perspective of the economic operators because it helps to reduce unfair competition.

7.7.1 Regulatory authorities

To ensure the impartiality of market surveillance operations, market surveillance is the responsibility of the state. The state therefore has to establish regulatory authorities to serve as its market surveillance infrastructure. The number of regulatory authorities and their fields of responsibility are decisions the state has to make. In most countries, each ministry will establish one or more regulatory authorities with specific mandates. Some countries, to better use scarce resources, will establish only four or five larger regulatory authorities for specific sectors (for example, food safety, manufactured products, telecommunication, transportation, building and construction, and so on). Very small countries may even consider the establishment of a single regional regulatory authority for all products falling within the scope of technical regulations. The choice will be determined by political custom and practice, availability of resources, and the extent of the work to be done.

The major issue for the market surveillance infrastructure is that there should not be obvious gaps and overlaps in the spheres of responsibilities of the various regulatory authorities. Gaps might allow products into the marketplace whose failure could be deleterious to the safety and health of the population or the environment. Overlaps, on the other hand, create uncertainty in the marketplace as suppliers are subjected to differing sets of requirements, resulting in unnecessarily high transaction costs for more than one regulatory authority. It is also debatable whether such duplication supports safety and health; the argument may even go in the opposite direction, because suppliers may take risks they otherwise would not have taken to circumvent one or another technical regulation.

Cooperation among the regulatory authorities is therefore important, and many countries have established supranational technical regulation coordination offices for this purpose (Jacobzone, Choi, and Miguet 2007). These offices also effect proper cooperation between the regulatory authorities and the various organizations in the QI that provide standards, metrology, accreditation, and conformity assessment services in support of the implementation of technical regulations. A further responsibility of these offices is to ensure that the country as a whole (that is, all ministries and regulatory authorities) complies with its obligations in relation to the WTO TBT Agreement.

Regulatory authorities should have the necessary resources and powers to conduct their surveillance activities. This is to monitor products placed on the market and, in cases of noncompliance, to take appropriate action to enforce conformity. The regulatory authority should have the appropriate number of suitably qualified and experienced personnel who have the necessary professional integrity. Testing should be conducted by technically competent (accredited) laboratories. The regulatory authority should also be free from undue political influence and carry out its responsibilities in an impartial and nondiscriminatory way.

7.7.2 Market surveillance principles

For market surveillance to be efficient, resources need to be concentrated where risks are likely to be higher or noncompliance more prevalent. On the other hand, regulatory authorities need to carry out market surveillance with due respect for the principle of proportionality. This means that action should be in accordance with the degree of risk, and the impact on the free movement of products should not be more than is necessary. Statistics and risk assessment procedures are a great help in getting this balance right.

Market surveillance normally does not take place during the design and production of the relevant product. In other words, suppliers should be responsible for premarket inspection, testing, or certification, as required by the relevant technical regulation (see section 7.6). Nevertheless, efficient enforcement usually requires collaboration with manufacturers or suppliers early in the process to ensure that nonconforming products are not placed on the market.

Market surveillance consists of scheduled activities and unscheduled investigations based on information from the marketplace or requests by authorities, a court of law, or written complaints by consumers. Typical market surveillance activities—consisting of (a) inspection of an audit sample of products falling within the scope of the relevant technical regulation, and (b) scrutiny of relevant documentation—therefore include the appropriate mix of the following:

- Planned regular visits to commercial, industrial, and storage facilities
- Planned regular visits to workplaces and other premises where products are put into service
- Random and spot checks
- Investigations of reported nonconformities
- Taking of audit samples of products and having them tested against the requirements of the technical regulation
- Requiring and reviewing all the necessary documentation

Voluntary product and management system certification can contribute to the reduction of risks. However, regulatory authorities should remain impartial regarding these certifications and may take them into consideration in a transparent and nondiscriminatory way only. Therefore, products with product certification marks or that are produced by companies with management system certification should not be excluded from market surveillance activities.

An issue that should not be forgotten when establishing market surveillance schemes is the question of controls at borders. In the global trading system, many products will be imported into the market of any given country. Many of these products will fall within the scope of technical regulations. The market

surveillance schemes should therefore also be extended to include products imported into the country, whether by boat, train, road, or air. The border controls will require even more careful planning to ensure that products are not held up unnecessarily at the border while being inspected for compliance with the relevant technical regulations. A system of bond warehousing is often implemented whereby products can be moved from the border to specific warehouses, but the products cannot be marketed until released by the regulatory authority.

7.7.3 Imposition of sanctions

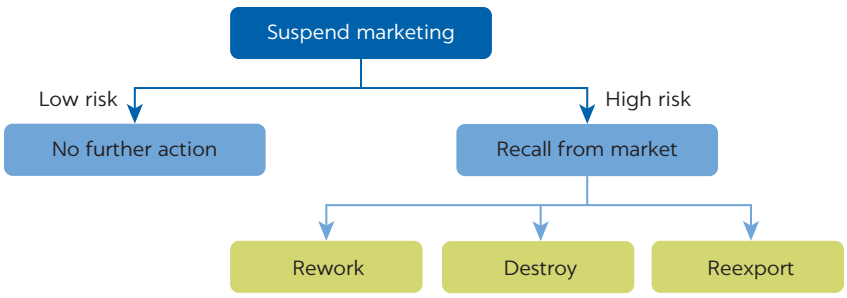
Regulatory authorities must take action to enforce conformity when nonconforming products are discovered in the marketplace. The corrective action will depend on the degree of noncompliance and should also follow the principle of proportionality. The difference between nonsubstantial and substantial noncompliance will frequently have to be based on the sound judgment of the regulatory authority. Small labeling errors, for example, can be considered as nonsubstantial, whereas noncompliance with requirements that may be deleterious to the health or safety of users must be considered as substantial.

Typical actions taken by the regulatory authority can be considered on a number of levels (figure 7.5):

- *Rectification:* In the case of nonsubstantial nonconformities, the regulatory authority prevails on the supplier to rectify all future products.
- *Suspension:* In the case of substantial nonconformities, any further marketing of the product must be suspended immediately.
- *Recall:* In serious cases, the supplier must recall nonconforming product from the marketplace, and consumers must be informed to return identified products to the point of sale.
- *Postrecall decisions:* A decision has to be made whether a recalled product can be rectified to render it compliant and be marketed again or whether the nonconformity is of such a nature that the product must be destroyed.

A decision to destroy a consignment should be mindful of the environmental impacts such an action would entail, and specialist companies may have to be contracted by the supplier to do so as directed by the regulatory authority. In some countries, the regulatory authorities direct the supplier to reexport noncompliant imported products to the country of origin. This decision should

FIGURE 7.5
Typical administrative sanctions against noncompliant products



be taken cautiously because once the product is no longer within the country's jurisdiction, it is anybody's guess as to where it will be exported. It may just end up in a country without a proper technical regulation regime, consequently bringing misery to the purchasers there.

If none of these administrative-type measures has the desired effect, the regulatory authority must take legal action, such as taking the offending party to court to enforce compliance in the marketplace. Until court proceedings are completed, the marketing of such products remains suspended, and consumers should be informed accordingly. Failure to do so may just give some suppliers the sense that the regulatory authority is unwilling to go to court, and rogue suppliers may just be strengthened in their resolve to circumvent requirements to gain greater profits.

7.8 IMPACT OF TECHNICAL REGULATIONS

The potential impact of implementing technical regulations could be profound. Yet there is no definitive conclusion about the impact of technical regulations on trade or on the safety and health of the population, fauna and flora, and the environment, even though many studies have been undertaken. All the studies have highlighted the challenges in getting meaningful answers because of the general lack of data (WTO 2012).

A few general trends have been identified in various studies. These studies mostly deal with nontariff barriers (as a whole, which include TBT and SPS issues). The following sections are summarized from the WTO's *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century* (WTO 2012).

7.8.1 Are nontariff measures on the increase?

Despite common perceptions about a rising trend in nontariff measures (NTMs), evidence is inconclusive.[6] NTMs appear to have risen in the mid-1990s; but between 2000 and 2008, activity remained relatively flat, before picking up again following the 2008–09 global financial crisis. However, WTO notifications suggest an upward trend in technical barriers to trade (TBT) and sanitary and phytosanitary (SPS) measures.

According to historical data from United Nations Conference on Trade and Development (UNCTAD) databases, shares of product lines and trade values covered by NTMs rose between the late 1990s and early 2000s but then stayed flat or declined slightly up to 2008. WTO data on notifications, however, show increasing use of TBT or SPS measures since the mid-1990s. This increase is also reflected in an increase in the number of specific trade concerns raised by WTO members in the TBT and SPS committees.

7.8.2 Most-burdensome NTMs: TBT and SPS measures

Evidence from business surveys conducted by the International Trade Centre (ITC) in 11 low- and middle-income countries suggests that TBT and SPS measures are the most burdensome for exporters (ITC 2015). In 2010, the share of TBT or SPS measures in all NTMs perceived as burdensome by exporting firms

was 48 percent. Similarly, survey-based data show a large share of TBT or SPS provisions in measures affecting EU exporters (just over 50 percent), but the U.S. share is lower (around 20 percent).

The impacts of TBT or SPS measures vary across sectors but are more prevalent in the agriculture sector, where even TBT concerns (29 percent) were the most prevalent NTMs, over and above the expected SPS concerns (ITC 2015). Evidence also suggests that procedural obstacles are the main sources of difficulties for exporting firms from low- and middle-income countries—time constraints and unusually high fees being the most-cited obstacles.

7.8.3 Impact of TBT and SPS measures on trade

The results from the current studies have shown that, in general, TBT or SPS measures have prevalently positive effects for more technologically advanced sectors but negative effects on trade in fresh and processed goods. The negative effects are generally the result of badly designed technical regulations or SPS measures as well as the less-than-effective or totally inconstant implementation thereof.

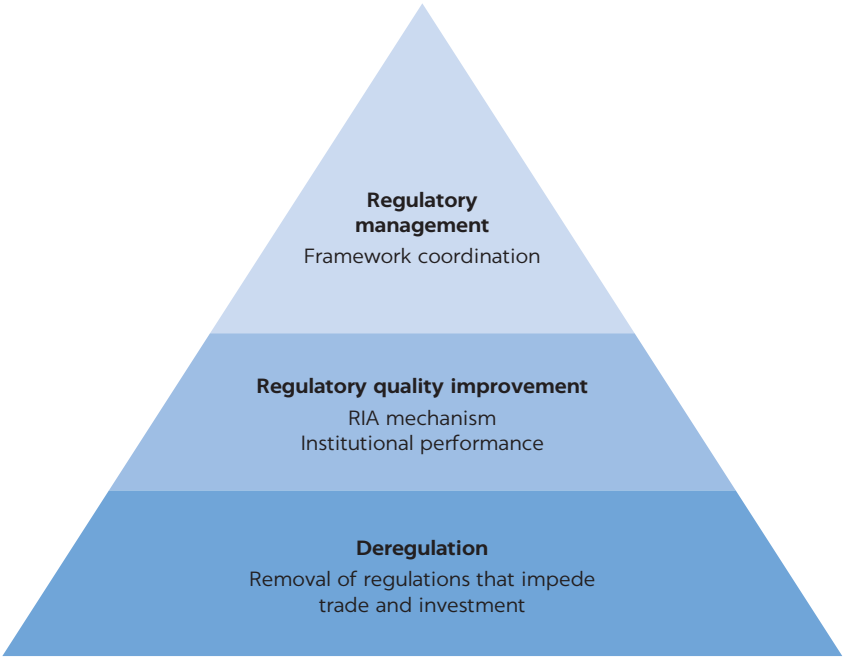
Furthermore, when negative, the effect of TBT or SPS measures on trade is found to be driven by the impact on low- and middle-income countries' exports, especially from small countries. There is some evidence that conformity assessment is particularly burdensome on food and agricultural trade, much more so than for manufactured goods. Larger firms in high-income economies are also less sensitive than smaller companies to TBT or SPS measures.

7.9 GOOD TECHNICAL REGULATORY PRACTICE

In most countries, technical regulations have been developed and implemented by any number of authorities over many years without official guidance as to their modalities. Hence, many countries have a real mix of technical regulations on the statute books, with some of them decades old. Many of these older ones are no longer relevant or are technically outdated, and they are sometimes even unknown to the authorities. Development and implementation modalities vary across regulatory authorities, and compliance with WTO TBT Agreement requirements is patchy or unknown. The technical regulation regime can therefore be considered as fragmented and disordered, and differences among regulatory authorities have the tendency to increase over time.

With the development of global trade and the necessity for countries to gain access to these markets, the need for regulatory reform of how technical regulations are developed and implemented has therefore become pressing. Good regulatory practices have to be established across all regulatory authorities, and all of these should follow similar patterns. A country needs to show a "single face" to the world regarding its technical regulations. This brings about clarity and consistency in the marketplace and is the better way to get rid of unnecessary trade-restrictive practices. Such regulatory reform can be divided into three phases: deregulation, regulatory quality improvement, and regulatory management (figure 7.6).

FIGURE 7.6
Phases of regulatory reform



Source: Racine 2011.
Note: RIA = regulatory impact assessment.

7.9.1 Deregulation

As a first step, all the existing technical regulations on the statute books should be identified. Once this is accomplished, the responsible ministries should establish a proper review of all current regulations and (a) *withdraw* them (if they are no longer relevant or if product integrity can be achieved with fewer regulatory controls); (b) *revise* them (if they are technically outdated); or (c) *confirm* them (if they are still necessary and technically relevant). Such a review program has to have a time limit; otherwise, it will drag on forever.

7.9.2 Regulatory quality improvement

It is possible, using a variety of scientific sources and methods, to arrive at fairly good estimates of the protection improvement likely to result from new or revised technical regulation. These estimates can be combined with information about the estimated costs of implementing such technical regulation to generate a regulatory impact assessment (RIA).

The second element of regulatory quality improvement has to do with the improvement at the technical, organizational, and performance levels of the many institutions that are involved in a modern technical regulation regime. These include technical regulation development, standards and conformity assessment issues, metrology, and accreditation—in fact, the totality of the QI.

7.9.3 Building a regulatory management system

Assessments in various parts of the world have highlighted a number of weaknesses in national technical regulation regimes that are in need of serious overhaul. Some of the common results from these assessments indicate the following:

- In most economies, technical regulations are developed and implemented by many ministries, authorities, or agencies, each of them following their own customs and practices.
- Authorities have developed their own unique ways of developing and implementing technical regulations over time, and these customs and practices may or may not comply with WTO TBT Agreement requirements.
- Invariably, overlaps and duplication developed among the authorities' spheres of responsibility and activity, and hence in the regulatory regimes as well.
- Regulatory authorities, having grown accustomed to a position of absolute power in the past, do not easily shift toward a more consultative approach.
- The use of voluntary standards as the basis for technical regulation is not the norm. In certain countries, the two are confused.

To deal with these weaknesses in a systematic way, an effective national regulatory management system has to be developed, agreed to at the highest political level, and rigorously implemented. Two important elements of such a regulatory management system are a technical regulation framework and a coordination mechanism.

Technical regulation framework

To ensure that the technical regulation regime of a country meets the requirements of the WTO TBT Agreement, it is good regulatory practice that the principles, approaches, and modalities for the development and implementation of technical regulations be harmonized across all ministries and regulatory agencies at the national and subnational levels. Such a coordinated approach is important for consistency in the marketplace and is useful in ensuring that the technical regulation regime is both effective and efficient.

The community legislative instruments of the EU New and Global Approach directives are probably the best-known exponents of such a technical regulation framework. The point is that such a consistent approach is only possible if the framework is given legal substance by a legislative instrument (such as a law, decree, or the like) that takes precedence over any other legislative instrument mandating that authorities develop and implement technical regulations.

The contents of the technical regulation framework can be deduced from the building blocks of a technical regulation (see section 7.3). They should therefore cover at least the following:

- The necessity of conducting an RIA to determine whether a technical regulation is necessary or whether the market failure can be dealt with in another way
- The way in which standards will be used as the basis for technical regulation

- The modalities for the demonstration of conformity
- The responsibilities of the regulatory authority—for example, premarket approvals, market surveillance, and the imposition of sanctions
- The type of sanctions to impose when nonconformities are discovered in the marketplace

The technical competency of conformity assessment bodies needs to be addressed—highlighting the role of accreditation and metrology. Also important is to stress the responsibilities of suppliers, not only in ensuring that products meet requirements and that the necessary conformity evidence is in place, but also in supporting the market surveillance activities of the regulatory authorities. The technical regulation framework will also establish a supranational technical regulation coordination office, if relevant (see below).

Technical regulation coordination office

Technical regulation is complex, and it has become one of the major issues hindering the movement of goods across borders and within countries. Because technical regulations are developed and implemented by many authorities at the national and even subnational levels, coordination of their responsibilities—among each other and between them and the QI organizations providing standardization, metrology, accreditation, and conformity assessment services—has become an imperative for trade facilitation.

Many countries have established supranational regulatory coordination entities (Jacobzone, Choi, and Miguet 2007). A typical organizational relationship between such a coordination entity and the ministries, regulatory authorities, and QI institutions for technical regulation activities is shown in figure 7.7. This example is by no means the only possibility, but it can serve as a useful departure point for national debate and decision making regarding such a construct. Even smaller countries—such as Costa Rica, the Czech Republic, and the Kyrgyz Republic—have established such coordination offices and mechanisms, and others are in the process of doing so.

It is important that such an office have the relevant legal and perceptual authority to deal with ministries and agencies that are powerful in their own right. Hence, it is usually accountable to the holder of a high political office, such as the prime minister or president (Racine 2011).

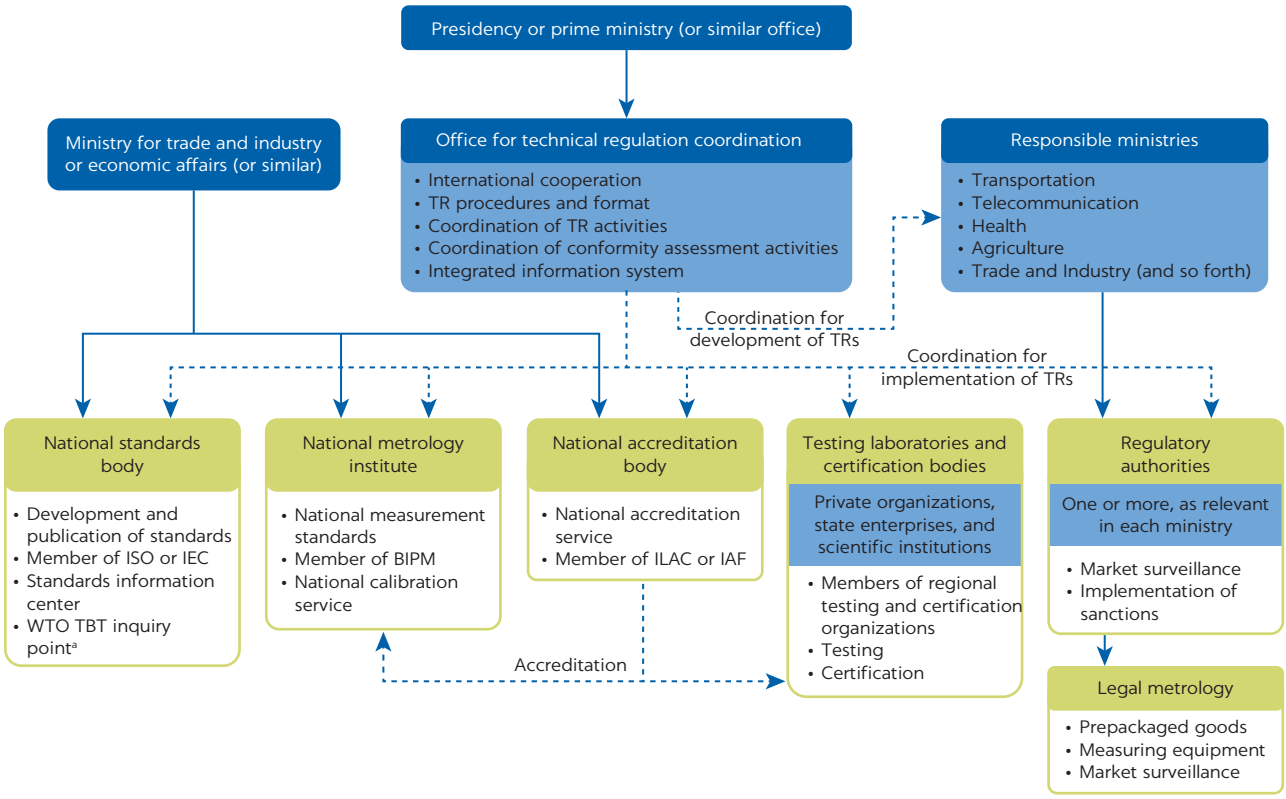
7.10 DIFFERENCES BETWEEN TBT AND SPS MEASURES

The terminology of standards, technical regulations, and SPS measures is frequently a source of confusion. Common usage of these terms does not always correspond to the legal meanings provided in the WTO TBT and SPS Agreements. For example, many countries have food standards that are mandatory, whereas the WTO TBT Agreement considers standards to be "voluntary" in nature. Furthermore, the WTO TBT and SPS Agreements differ slightly in the meaning of the word "standard"; in the WTO TBT Agreement, a standard is purely voluntary, whereas in the WTO SPS Agreement, a food standard could be mandatory.

It is important to understand that the WTO TBT and SPS Agreements are complementary but mutually exclusive. A measure falling within the scope of the WTO SPS Agreement is by definition excluded from the WTO TBT Agreement.

FIGURE 7.7

Typical organizational relationships between QI service providers and technical regulation authorities



Source: Racine 2011.
Note: Dotted lines denote coordination relationships; continuous lines denote oversight relationships. BIPM = International Bureau of Weights and Measures; IAF = International Accreditation Forum; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; QI = quality infrastructure; TR = technical regulation; WTO TBT = World Trade Organization Agreement on Technical Barriers to Trade.
a. An "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 a subject such as technical barriers to trade or sanitary and phytosanitary measures.

An important point is that it is the *measure* that is mutually exclusive, not the *product*. There are numerous examples of products that are subject to both the WTO TBT Agreement and the SPS Agreement, depending on the product characteristic that is being dealt with (table 7.1). Another common fallacy is that food products are subject only to the WTO SPS Agreement. This is not true, either. The WTO TBT Agreement is applicable not only to manufactured products, but also to agricultural products insofar as they are not subject to an SPS measure.

The WTO SPS Agreement defines an "SPS measure" as any measure to

- Protect human life or health from risks arising from additives, contaminants, toxins, or disease-causing organisms in food and beverages, or from diseases carried by animals or plants or their products, or from pests;
- Protect animal life or health from risks arising from additives, contaminants, toxins, or disease-causing organisms in feedstuffs, or from diseases carried by animals or plants, or from pests, diseases, or disease-carrying organisms;
- Protect plant life or health from pests, diseases, or disease-causing organisms; and
- Protect or limit other damage to a country from the entry, establishment, or spread of pests.

TABLE 7.1 Selected comparisons between typical SPS and TBT measures

CATEGORY	COVERAGE OF SPS MEASURES	COVERAGE OF TBT MEASURES
Food and drink	• Additives in food or drink • Contaminants in food or drink • Toxic substances in food or drink • Residues of veterinary drugs or pesticides in food or drink • Processing methods with implications for food safety • Labeling requirements directly related to food safety	• Labeling on composition or quality of food or drink • Quality requirements for fresh food • Weight, volume, shape, and appearance of packaging for food or drink
Plants and animals	• Plant and animal quarantines • Declaration of areas free from pests or diseases • Prevention of the spread of pests or diseases to or within a country	• Packaging and labeling of dangerous chemicals and toxic substances, pesticides, and fertilizers
Manufactured goods	n.a.	• Electrical safety of appliances • Vehicle safety • Safety of toys • Labeling of textiles and garments

Sources: "Understanding the WTO Agreement on Sanitary and Phytosanitary Measures," World Trade Organization (WTO), May 1998, https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm; O'Connor and Company 2002; World Bank.
Note: n.a. = not applicable; SPS = sanitary and phytosanitary; TBT = technical barriers to trade.

Some of the elements of food standards enforced by governments to ensure the safety of foods and the biosecurity controls enforced at international borders to keep out exotic animal and plant pests are typical SPS measures. The differences between SPS and TBT measures are further elaborated in table 7.1 through a few examples dealing with food, safety, and health.

The WTO SPS Agreement requires that WTO members base their SPS measures on the international standards, guidelines, and recommendations developed by three specific organizations: the Codex Alimentarius Commission (CAC), the World Organisation for Animal Health (OIE), and the Secretariat of the International Plant Protection Convention (IPPC). The WTO TBT Agreement also requires that WTO members base their technical regulations on international standards, without specifically mentioning any international standards body by name. Furthermore, WTO members shall ensure that any SPS measure is based on scientific principles and is not maintained without sufficient scientific evidence. The WTO TBT Agreement does not specifically mention such a focus on scientific principles when deciding on whether to implement a technical regulation; it broadly lists only valid reasons.

NOTES

1. The WTO SPS Agreement lists three international standards bodies by name: the Codex Alimentarius Commission (CAC), the International Plant Protection Convention (IPPC), and the World Organisation for Animal Health (OIE).

2. The EU's so-called New Approach to technical harmonization and standards was introduced in 1985. For more information, see "New Approach and Other Directives," European Committee for Standardization (CEN) website: https://www.cen.eu/work/supportLegislation/Directives/Pages/. Harmonized standards are European Norms (EN)—referring to either the German or French equivalent of a European standard—that are elaborated by the European standardization bodies under a mandate from the European Commission.
3. The EU has published a number of directives detailing the requirements for "notified bodies," but the EU member state decides which conformity assessment bodies under its jurisdiction it wishes to "notify" for a specific directive. The "notified body" is answerable to the competent authority in the EU member state.
4. The IEC schemes for electrical and electronic products are as follows: IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE); IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx); IEC Quality Assessment System for Electronic Components (IECQ); and IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications (IECRE).
5. The CE marking is placed on the product and/or packaging by the manufacturer or supplier once all the requirements of the relevant new directive of the EU have been fulfilled, thereby denoting that the manufacturer or supplier takes full responsibility for the compliance of the product with specified requirements.
6. A nontariff measure (NTM) is a regulatory requirement other than tariffs imposed by a country on traded products. If the NTM has a marked and unnecessary negative effect on trade, then it becomes a nontariff barrier (NTB). Not all NTMs become NTBs, but many have the potential to do so.

STANDARDS REFERENCED IN MODULE 7

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