6

Conformity Assessment

6.1 CONFORMITY ASSESSMENT SPECTRUM AND DEFINITIONS

Conformity assessment is the collective term for a number of services based on the core functions of the quality infrastructure (QI): standards, metrology, and accreditation. It is defined as the demonstration that specified requirements of a product, process, system, person, or body are fulfilled in ISO/IEC 17000 ("Conformity Assessment") of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). The specified requirements may typically be stated in regulations, standards, and technical specifications.

Generally speaking, the elements of conformity assessment include inspection, testing, and certification used in all fields of investigation, innovation, process improvement, productivity, product development, product compliance, and many more. In some quarters, calibration is also considered conformity assessment, but it is not. Calibration belongs firmly within the metrology environment (as covered in module 4: Metrology).

6.2 INSPECTION

Inspection is the examination of a product design, product, process, or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Inspection of a process may include inspection of persons, facilities, technology, and methodology (ISO/IEC 17000).

Inspection therefore includes the concepts of information gathering (which could include testing and measuring), observation (including the conditions), and forming a judgment on the suitability for use or compliance with requirements. Judgment is an essential element of the process, and therefore inspection could be prone to some variability of outcome. For this reason, it is crucial that inspectors are thoroughly trained for the sectors in which they are expected to work.

TABLE 6.1 Users of inspection in trade-related activities

CATEGORY OF ACTIVITY INSPECTED	MANUFACTURER	CUSTOMER	REGULATOR	TRADER
Process control	X			
Compliance in relation to safety and other regulatory issues	X	X	X	X
Design verification		X	X	
Installation of a major plant		X	X	
Commission of a major plant		X	X	
Maintenance		X	X	
Quantity	X			X
Quality	X	X		X

Source: ITC 2011.

The definition also indicates that inspection is not limited to products or their manufacturing processes. Inspection is also applied in diverse activities such as design verification, installation and commissioning of equipment, in-service monitoring, regulatory affairs, financial auditing, and failure investigations. Table 6.1 provides an overview of the interests of organizations that use inspection in trade-related matters as an example of the wide application of inspection.

Such a variety of applications demands a careful consideration of the use of the term "inspection." For example, in quite a few economies, inspection is mostly used in the context of regulatory work, whereas in others it also covers commercial supervision by third-party bodies and in-house production control by the manufacturer.

6.2.1 Scope of inspection

Inspection is not limited to manufacturing processes or products. It is also widely used in such diverse activities as design verification, regulatory affairs, financial auditing, and failure investigation in both the regulated and nonregulated domains. In some economies, inspection is understood and mostly used in the context of regulatory control, while in reality it also covers commercial supervision by third-party bodies and in-house production control by manufacturers, as in the following cases:

- *In regulatory control,* inspection includes both premarket and in-market surveillance of products subject to technical regulations, for example. Inspection of the regulatory kind could also include the regular examination of products and installations for safety purposes, such as motor vehicles, cranes and lifting gear, lifts and escalators, boilers and pressure vessels, and electrical installations.
- *In the manufacturing sector,* inspection is an essential element of manufacturing control, and it includes testing and gauging or measurement. It includes the inspection of raw materials and components before production starts, physical examination of in-process product to assess its fitness to proceed in the manufacturing process, and the final inspection of the product before it is dispatched. Inspection departments are sometimes also responsible for calibrating process control instrumentation.

- *In complex manufacturing* (manufacture of complex products, assemblies, or installations) or if a product may have dire safety or economic consequences for the customer if it does not meet specified requirements, it is not uncommon for customers to either conduct their own inspections in parallel to the inspections of the manufacturer throughout the production cycle or to engage a specialized third-party inspection body to represent their interests. In such cases (for example, in shipbuilding, aircraft manufacturing, production installations, and the like), the customer will pay great attention to the inspection systems employed by the manufacturer and the management of those systems. Some of these inspection systems may also be defined in technical regulations (for example, regarding boilers and pressure vessels).
- *In export markets,* the government of an economy building its image as a high-quality manufacturer may deem it appropriate to institute inspection programs to ensure the quality of exported products. This was a key strategy for Japan for its optical sector, for example, implementing such export inspection after World War II and maintaining it for a few decades until the Japanese optical sector developed to the point where it conquered world markets.
- *In import markets,* a number of countries impose import inspection for the safety and health of the population, fauna and flora, and the environment. This could be in the form of inspection of imported goods at the border, but often multinational inspection organizations are contracted by the government to conduct such inspections at the source (preshipment inspection).

The scope of inspection is therefore extremely large and varied and is implemented by manufacturers, purchasers, and regulatory authorities alike. The latter may include regulatory authorities for products and legal metrology.

6.2.2 Types of inspection bodies

Inspection bodies can be in either the public or private sector. Whereas public sector inspection bodies are mostly engaged in regulatory-type work, private sector inspection bodies cover a vast spectrum of inspection activities in both the regulatory and nonregulatory domains. Three types of inspection bodies are generally recognized and defined in the relevant international standard (ISO/IEC 17020) on the basis of their formal separation from possible sources of influence (figure 6.1):

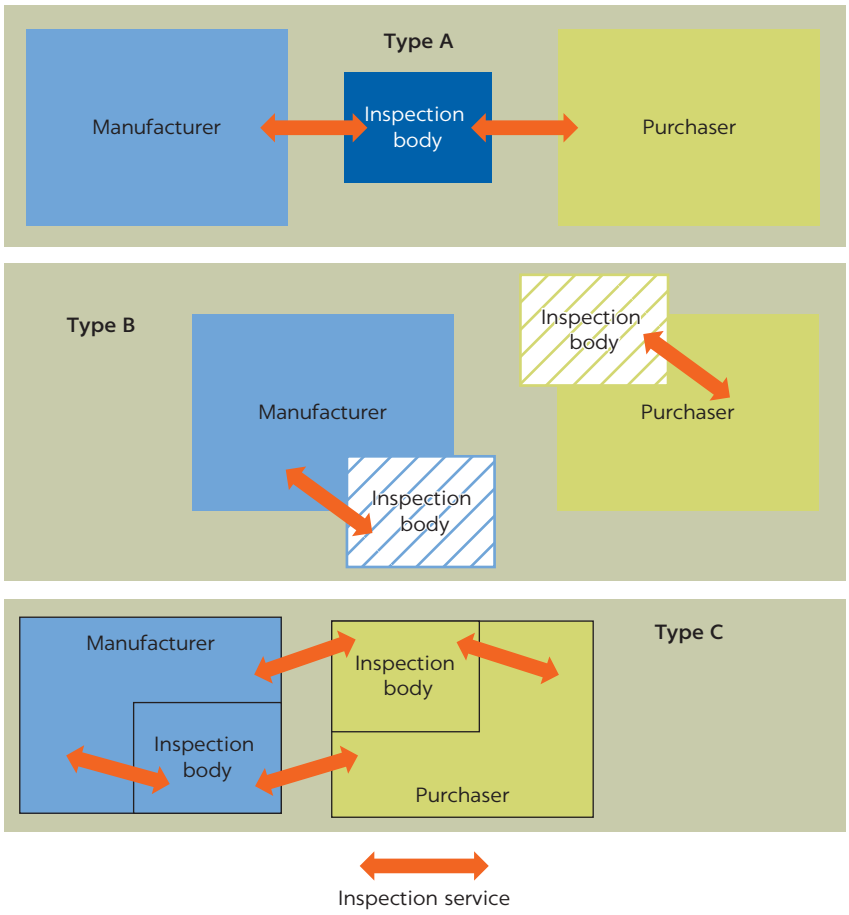
- *Type A:* Third-party inspection bodies not directly linked to the organization involved with the design, manufacture, use, or maintenance of items subject to inspection
- *Type B:* First- or second-party inspection bodies that are part of a supplier or user, forming an identifiable and separate part of the parent organization and providing only in-house inspections to the parent
- *Type C:* First- or second-party inspection bodies forming an identifiable, but not necessarily separate, part of the parent and providing inspection services to the parent organization or others

ISO/IEC 17020 also lists specific requirements regarding the impartiality of each part:

- *Type A inspection bodies* must be independent from both the supplier (first party) and the purchaser (second party) and not even remotely part of their legal identities. Furthermore, they must not directly be involved in the design,

FIGURE 6.1

Types of inspection bodies defined by ISO/IEC 17020



Note: ISO/IEC 17020 is the standard, "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." Types A, B, and C are defined on the basis of the extent of formal separation from possible sources of influence. *Type A* refers to third-party inspection bodies; *Type B* to first- or second-party bodies that are an identifiably separate part of the parent organization and supply only in-house inspections; and *Type C* to first- or second-party bodies that are an identifiable, but not necessarily separate, part of the parent and supply inspections to both the parent and others.

manufacture, supply, installation, purchase, ownership, use, or maintenance of the items to be inspected, nor should they be organizationally linked to any of the parties involved in the design, manufacture, supply, installation, purchase, ownership, use, or maintenance of the items to be inspected.

- *Type B inspection bodies* shall supply inspection services only to the organization of which the inspection body forms a part. This could be either the supplier or the purchaser. But a clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the inspection body within the parent organization. The inspection body and its personnel shall not be engaged in the design, manufacture, supply, installation, use, or maintenance of the items inspected.

- *Type C inspection bodies* form an identifiable, but not necessarily separate, part of the supplier (first party) or the purchaser (second party). They may provide inspection services to either the supplier or the purchaser and shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities. In other words, the design, manufacture, supply, installation, servicing, or maintenance of an item and the inspection of the same item carried out by a Type C inspection body shall not be undertaken by the same person. The inspections of Type C inspection bodies are not considered third-party inspections like the other two.

6.2.3 Relationship of inspection with other conformity assessment services

The international standard ISO/IEC 17020 has been developed considering inspection as a stand-alone activity. From its various uses as described above, it is quite clear that some form of inspection is frequently combined with, or part of, other conformity assessment services, such as product certification (see section 6.4) and testing (see section 6.3). When inspection is part of another conformity assessment activity, it may be necessary to adjust the requirements in ISO/IEC 17020 depending on inspection's role in the activity. Relationships between inspection and other conformity assessment activities that need to be considered, when relevant, include the following:

- When an inspection is used to reach a conformity assessment decision about the specific product being inspected, inspection may use testing, a service that should comply with ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories") to inform this decision. Product certification also relies on testing in accordance with ISO/IEC 17025 and even on inspection to inform the product certification decision. But product certification differs from inspection, in that it provides for the certification of an ongoing series of products where they are subject to a range of conformity assessment activities, whereas inspection determines compliance of only the inspected product.
- With product certification, the supplier is always the customer of the certification body, whereas with inspection the customer could be the supplier, the purchaser, or somebody else (such as a regulatory authority). The goal of product certification is to give confidence to the market regarding the supplier's capability of meeting the product requirements continuously. Hence, the certification body's decision will always rely heavily on its confidence regarding the supplier's control of the manufacturing process—confidence that is demonstrated by the supplier's quality control or quality management systems. The aim of inspection is only to give the party on behalf of which the inspection body is acting information on the compliance of the actual product being inspected.
- In product certification, when a certification body finds a nonconforming product during surveillance visits to the supplier or the market, it will require the supplier to implement corrective action to ensure that all future products comply. The certificate is not immediately withdrawn. If a product is found to be noncompliant during an inspection, the product is rejected; a certificate of compliance is not issued. Depending on the circumstances, the supplier

may have to replace the product, repair it, or lose the sale. Obviously, if the inspection takes place in-house during the manufacturing process, corrective action has to implemented to rectify the problem also for future products, which may include changes to the manufacturing process or controls.

- The scope of ISO/IEC 17020 does not cover quality management system certification. It may, however, be necessary for inspection bodies to examine certain aspects of the quality management system or other documented systems to justify the inspection results—for example, in the examination of processes.
- The scope of ISO/IEC 17020 also does not cover personnel certification activities. It may, however, be necessary for inspection bodies to consider aspects of the qualification of personnel (as inspectors or in the course of their inspections) to justify the inspection results.

6.3 TESTING

Testing is the determination of the characteristics of a product or commodity and, in the QI context, the evaluation thereof against the requirements of a standard (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). The output of a test laboratory is a test report or a test certificate. The scope of testing is immense, and it ranges from mechanical, electrical, metallurgical and civil engineering, and biological and chemical sciences to food technology, fiber technology, and many other areas.

Testing can be of a destructive or a nondestructive nature. It can be mundane, extremely complex, or anything in between. It can involve routine, state-of-the-art, or cutting-edge technology. Although testing is usually seen as taking place in a laboratory, it can also take place in the field or on-site following delivery and installation.

In short, the scope of testing is extremely wide. There are, however, some parameters that determine the integrity of testing services irrespective of the level of complexity or technological development (UNIDO 2011).

6.3.1 Uses of testing

The results of testing are used for many purposes. It is also important to realize that the boundaries between testing and inspection are sometimes quite blurred because there is some overlap; the same activity may be labeled as being in either field depending on country practices (as discussed earlier, in section 6.2). Some of the uses of testing include the following:

- Testing may provide adequate information to permit a conclusion on whether a product or commodity complies with requirements specified by regulatory authorities, purchasers, or other users.
- Testing of a prototype product is part and parcel of product certification, as is the continuous testing of samples of the subsequent production (see section 6.4).
- Testing of each individual product may be a prerequisite for the certification of low-volume, high-risk products such as medical devices or products for use in explosive environments.

- Testing is very much part of production control throughout the production value chain to ensure that completed products meet specifications and standards.
- A substantial amount of testing is concerned with data collection for scientific purposes, medical prognosis, and law enforcement rather than product compliance (for example, environmental measurements, testing of blood samples, and so on).

As manufactured goods become more technically sophisticated and market demand grows more stringent, testing will become an increasingly important part of trade protocols and trade agreements. The move to freer movement of goods, on the other hand, will call for a greater recognition of testing carried out in the country of origin, but this can happen only if end users have confidence in the competence of laboratories conducting tests in the first place. The ultimate objective is to have the product inspected, tested, or certified once and recognized everywhere.

6.3.2 Demand assessment

In a well-developed market economy, testing services are provided by a multitude of testing laboratories in both the public and private sector domains. These are exposed to market forces, just like any other service, to satisfy the needs of the country or markets. In low- and middle-income economies, however, this may not yet be the case. In such economies, the state is often required to establish and maintain the bulk of the test laboratories before a self-perpetuating market for testing has developed. Depending on a cost-benefit analysis, it may even be more cost-effective to send test samples to an existing laboratory outside the country rather than establishing one in the country.

A proper assessment as to the real needs of the authorities and industry is indicated. This should also include an overall assessment of the country's laboratory capacity, whether latent or active. Where they exist, regional laboratories should also be factored into the considerations. The information from such an assessment is an extremely useful point of departure for planning the further development of testing capacity in the country, the role of government in this respect, and the division of labor. The last is extremely important to counter the tendency of ministries, together with the donor community, to each establish their own public laboratories without regard to the unnecessary and costly duplication of resources.

This duplication has some further negative consequences, in that the financial sustainability of the individual laboratory is compromised, the small pool of trained laboratory personnel is stretched, and the amount of work in the country is barely enough to even keep one laboratory operating at an optimum capacity—with dire consequences for the quality of testing services among all of them.

6.3.3 Premises and environmental controls

Many testing laboratories are subject to some very specific accommodation requirements—for example, separating functions to ensure that no cross-contamination of samples can occur, separating laboratory space and offices to

ensure that personnel spend only testing time in the laboratories, and so on. In addition, most product testing follows the same rule: same temperature, same humidity, same altitude, same test speed, same test force, same test sequence, same number of test cycles, and so on.

Testing of textiles and polymers to ISO standards, for example, requires an environment of 20 ± 2 degrees Celsius and 65 ± 2 percent relative humidity. For paper and many rubber products, the requirement is 23 ± 1 degree Celsius and 50 ± 2 percent relative humidity. On the other hand, most mechanical and electrical engineering testing can be conducted at 15–30 degrees Celsius with a relative humidity not exceeding 70 percent. Continuity of electricity supply (24 hours per day, 7 days per week) is of major importance when tight environmental controls are to be maintained. These requirements need to be carefully articulated and provided for when building new premises or refurbishing old ones.

Another issue that is often overlooked when laboratories are designed in the Northern Hemisphere is the window orientation: the sun comes from the south; hence the main windows are oriented to the north so that the sun does not shine directly into laboratories. In the Southern Hemisphere, this situation is reversed: the sun comes from the north; hence the main windows should be oriented to the south. Architects appointed from donor countries—generally from the Northern Hemisphere—have to be sensitized regarding this issue. Otherwise laboratories are built with windows that are incorrectly oriented, resulting in impossible environmental control and a tendency for "hot spots" to develop.

6.3.4 Test equipment and consumables

Procurement of any test equipment has to be preceded by a clear choice of the particular test methodology to be applied. This is to ensure that the test equipment meets the test methodology requirements in all aspects, not just the preferences of the testing staff. It must be able to deliver test results under similar conditions that are consistent with results from other laboratories. The same applies to consumables that affect testing operations, such as the quality of gases, availability of chemicals, and so on.

A second major issue for low- and middle-income economies is the availability of maintenance and technical support for a particular make of test equipment. In this respect, it often is more useful to purchase a slightly more expensive piece of test equipment, but one for which maintenance is available, than to take the less expensive option for which no technical backup is obtainable in the country or in neighboring states.

6.3.5 Electricity supply

Electricity supply in many low- and middle-income economies does not meet the generally accepted stability criteria existing in high-income economies, for example, ±5 percent variance on voltage. In low- and middle-income countries, this variance can be as large as ±15 percent, interspersed with frequent electricity supply failures. Additional voltage stabilizers and uninterruptible power supply (UPS) equipment may need to be provided; otherwise, equipment may not perform to expectations or may even be damaged by voltage fluctuations.

6.3.6 Calibration and certified reference materials

Calibration of test equipment needs to be properly addressed. This presupposes a functioning metrology infrastructure within the country or access to one in a neighboring country. In addition, some test equipment has to be calibrated by using certified reference materials (CRMs) (discussed in module 4: Metrology, section 4.3.4) that are frequently available only from limited sources and are always costly. The long-term availability of such CRMs has to be assured, which often has more to do with the availability of scarce foreign exchange to pay for the CRMs than anything else. Obtaining customs clearance for toxic reference materials poses additional challenges.

6.4 PRODUCT CERTIFICATION

Product certification is the mechanism whereby a certification organization attests that products—either a batch or the continuous production thereof—have been inspected and tested by it and that the products collectively comply with specified requirements, usually contained in a standard (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). The attestation by the certification body is in the form of a certificate supported by a product certification mark that the manufacturer is entitled to affix on the product after being licensed to do so. The certification body therefore visibly endorses the quality of the product.

6.4.1 Product certification bodies and marks

Product certification services are offered by many certification bodies—in both the public and private sectors, at both national and international levels, and providing services in both the regulated and nonregulated domains. In low- and middle-income countries, the national standards body (NSB) is frequently the only organization offering a product certification service with any market relevance. The NSB's product certification mark is generally known as the national product certification mark. In high-income economies, product certification is provided by private sector certification bodies more so than NSBs, eventually leading to the total withdrawal of the state in many instances.

Because product certification requires immense marketing resources for a specific product certification mark to become well known and trusted by consumers in more than one country, multinational product certification bodies have developed in recent decades. National product certification marks, on the other hand, often find it difficult to gain market acceptance outside their countries of origin.

Product certification marks cover many types of products or product characteristics. Typical examples include the following, among many others:

- The British Standards Institution (BSI) Kitemark for general products, United Kingdom
- The South African Bureau of Standards (SABS) mark for general products, South Africa

- The Geprüfte Sicherheit (GS, for "tested safety") mark for product safety, Germany
- The Association for Electrical, Electronic & Information Technologies (VDE) mark for electrical and electronic equipment, Germany
- The Underwriters Laboratories (UL) mark for product safety, United States
- The American Society of Mechanical Engineers (ASME) mark for pressure vessels, United States
- The Canadian Standards Association (CSA) mark for general products, Canada
- The Keuring van Elektrotechnische Materialen te Arnhem (KEMA, for "Inspection of Electrotechnical Materials in Arnhem") mark for electrical equipment, Netherlands
- AGMARK for agricultural products, India

It must be noted that the ubiquitous Conformité Européenne (CE) marking is not a product certification mark but a regulatory device of the European Union (EU).[1]

6.4.2 Product certification schemes and processes

The process for product certification will always include an assessment of the product, whether sampled at the factory, from the batch, or from the marketplace. It may include an audit of the manufacturing process initially or on a continuous basis, or it may just be based on surveillance testing in the marketplace. Compliance with international standards for quality management systems such as ISO 9001 ("Quality Management Systems—Requirements") or hazard analysis and critical control points (HACCP) may be required, or manufacturing controls may be defined specifically for the product by the certification body.[2] Once compliance has been demonstrated, the manufacturer may be licensed to affix the product certification mark on the relevant product, on the packaging, or both, thereby denoting compliance with the standard and the endorsement of the certification body.

The various product certification schemes are defined in ISO/IEC 17067 (table 6.2), and the process is shown graphically in figure 6.2.

Which type of product certification scheme would be the most appropriate in a given situation will depend on circumstances, the mode of operation of the certification body, the sophistication of the industry sector, and other factors; there are no definitive rules. Type 1 (batch inspection) and type 6 (services) are clear. Types 4 and 5 are similar, in that both the product and the production process are considered. In type 4, the production is subject to process control, whereas type 5 requires a complete management system that includes process control. Type 4 is sometimes used for small and medium enterprises (SMEs) that do not have the resources for a quality management system, whereas type 5 is used for the more sophisticated industries.

Some certificates for schemes other than 1a or 1b would be valid for a limited period (typically one to three years), after which the certification body conducts a more in-depth review, rather than surveillance audits, and reissues the certificate. Other schemes have no time limit; as long as the certified organization pays the annual certification fees and surveillance audits do not identify major nonconformities that are not dealt with promptly, the certificate stays valid.

TABLE 6.2 Product certification schemes (ISO/IEC 17067)

SCHEME TYPE	DESCRIPTION
1a. Type certification	One or more samples are subjected to determination activities. A certificate of conformity is issued for the product type. Subsequent production is not covered.
1b. Batch certification	A representative sample is selected from a batch of products and subjected to determination activities. If the outcome is positive, the whole batch is certified.
2. Open market surveillance	Periodic samples of the product are taken from the marketplace and subjected to determination activities, after which the products are certified. The scheme identifies continuous conformity throughout the distribution channel, but the resources required are substantial. Effective corrective measures in the case of nonconformities may be limited.
3. Product testing in the factory	Periodic samples of the product are taken from the point of production and subjected to determination activities, after which the products are certified. The surveillance process may include a periodic assessment of the production process. The impact of the distribution channel is not known, but nonconforming products may be identified before distribution.
4. Product testing in the factory and from the market	Periodic samples are taken from the point of production, from the market, or both and are subjected to determination activities, after which the products are certified. The surveillance includes periodic assessment of the production process. The impact of the distribution channel on product quality is provided for, as is a premarket mechanism to identify nonconformities. Duplication of effort may take place for products that are not affected by the distribution process.
5. Product testing combined with quality assurance	A quality management system must be in place. After initial type testing, periodic samples are taken from the point of production, from the market, or both and are subjected to determination activities. The surveillance includes periodic assessment of the production process and the quality management system. The extent to which the four elements are used in surveillance depends on the definition of the scheme and on circumstances.
6. Services and processes	Determination activities consider intangibles (such as service quality, time delays, management responsiveness, and so on) and tangibles in service quality support (such as cleanliness of vehicles, process controls, and so on). The surveillance includes periodic assessments of both the management system and the quality of the service or process.

Note: ISO/IEC 17067 is the standard, "Conformity Assessment—Fundamentals of Product Certification and Guidelines for Product Certification Schemes" (ISO and IEC 2013).

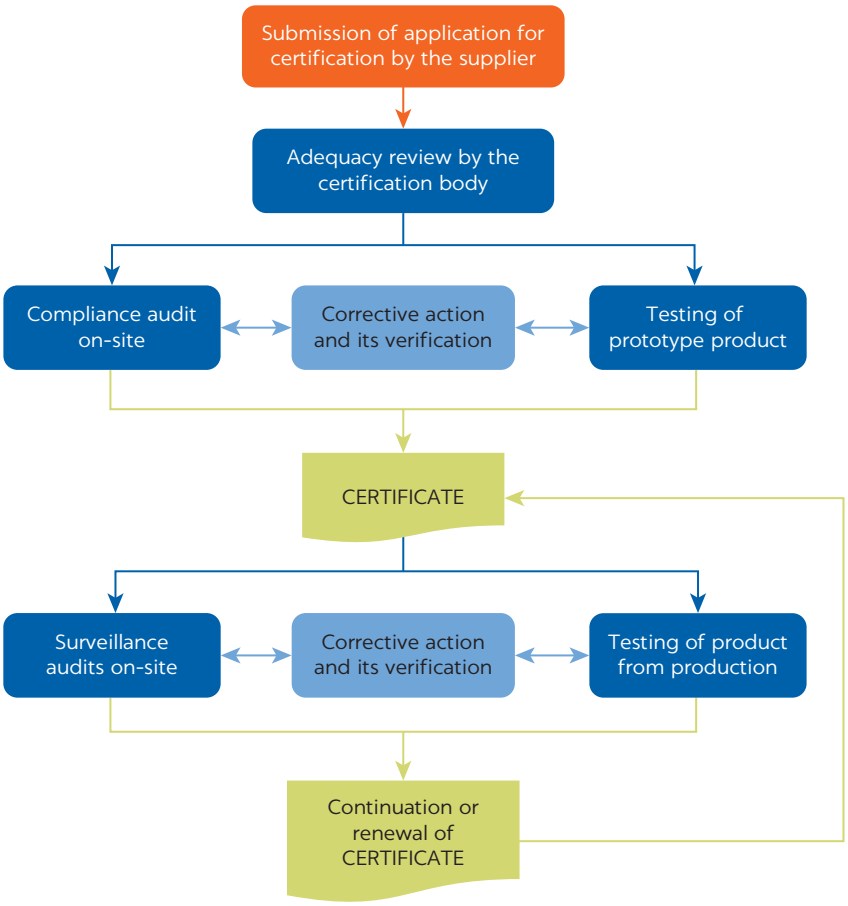
Obviously, the manufacturer has to pay for the certification process. Payments will have to cover the product testing (initial and control tests after licensing), the initial and surveillance audits of the manufacturing process, review of the clearance of nonconformities found during audits and testing, and an annual license fee. The license fee may be a flat fee, but it is more generally related to production volumes—that is, the number of units produced with the product certification mark. Typical product certification costs are in the region of 0.5–2.5 percent of production costs.

6.4.3 Value of product certification

Product certification, especially national product certification marks, have for many years been used as a requirement for products falling within the scope of technical regulation before they could be legally put on the market. This approach was fine when products were manufactured only in the country, but it has fallen out of favor in the global economy with massive products and services moving across borders. It is now seen as a restrictive trade practice, arguably noncompliant with the principles of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).

Hence, many countries are under pressure to change the system of mandatory product certification for regulatory purposes into a more modern technical

FIGURE 6.2
Schematic of the product certification process



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regulation approach (see module 7: Technical Regulation, section 7.5). But this has become a real challenge for the NSBs in those countries because the bulk of their income emanates from such mandatory product certification practices, and changing the system will result in some serious pressure on their business models.

Product certification has remained topical at both the national and multinational levels, in spite of its associated costs, for the following reasons:

- The manufacturer wishes to build its reputation, expand its market share, gain access to new markets, improve competitiveness, or promote new products by leveraging the trusted position of the specific product certification mark in the target market.
- The purchaser (for example, the individual, wholesaler, manufacturer, public procurement organization, importer, supplier, or employer) wishes to have an independent guarantee of the quality of the product purchased and of its compliance with known standards.
- In some countries, product certification marks, even though not mandatory, are considered evidence of compliance with technical regulation requirements insofar as the technical regulation and the standard against which the

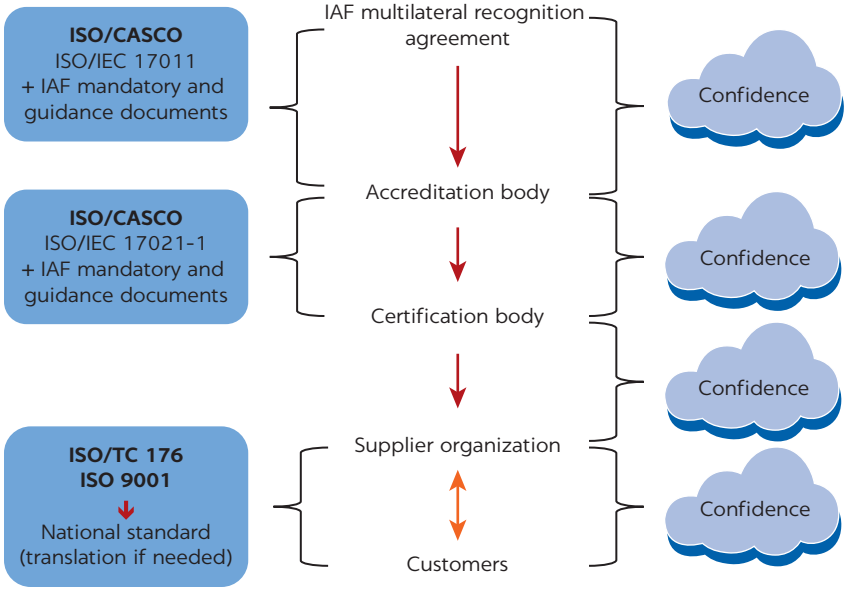
product is certified are equivalent. The CSA mark (for electronic products in Canada), the ASME mark (for pressure vessels in the United States), the BSI mark (for liquefied petroleum gas [LPG] cylinders in India), and the Tanzania Bureau of Standards (TBS) mark (for compulsory standards in Tanzania) are typical examples (UNIDO 2011).

6.5 MANAGEMENT SYSTEM CERTIFICATION

Management system certification is all about building confidence in the supplier, and it is the mechanism whereby a certification organization attests that a management system of a manufacturer, producer, supplier, or service provider has been assessed by it and that the management system complies with specified requirements, usually contained in a standard (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles").[3] The attestation by the certification body is in the form of a certificate, frequently supported by material that the certified company can use in marketing. The certification body therefore also visibly endorses the management system of the supplier. The certification organization, in turn, is accredited, thereby completing the "chain of confidence" (figure 6.3).

Whereas product certification is important for the supplier-consumer relationship (as its outcome defines the product quality), management system certification is more of a business-to-business issue, with the product standard being

FIGURE 6.3
"Chain of confidence" of system certification for ISO 9001



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Note: IAF = International Accreditation Forum; ISO/CASCO = International Organization for Standardization Committee on Conformity Assessment; ISO/TC 176 = ISO Technical Committee 176 (*Quality Management and Quality Assurance*); ISO 9001 = "Quality Management Systems—Requirements"; ISO/IEC 17011 = "Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"; ISO/IEC 17021-1 = "Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems."

defined in contracts or other purchasing arrangements. The management system certification denotes the capability of the supplier to continuously provide products or services complying with contractual obligations; it does not assess or make any claims about the product quality per se. Hence, the management system certification emblem should not be affixed to the product, because it does not denote product compliance.

6.5.1 Management system standards

The best-known management system certification schemes are based on ISO 9001 ("Quality Management Systems—Requirements"), for which more than 1 million certificates have been issued worldwide since its introduction in the late 1980s. Other international standards, and a growing number of private standards, are also used for management system certification (table 6.3). Some are important in specific sectors of the economy; others are of a more general nature.

TABLE 6.3 Selected management system certification schemes

LEVEL	SECTOR	STANDARD
International standard	Generic	ISO 9001:2015
	Environmental	ISO 14001:2015
	Food safety	HACCP
		ISO 22000:2005
	Information security	ISO/IEC 27001:2013
	IT service management	ISO/IEC 20000-1:2011
	Medical	ISO 13485:2016
	Supply chain security	ISO 28000:2007
	Petroleum and gas	ISO/TS 29001:2010
	Energy	ISO 50001:2011
Private standard	Aerospace	AS 9100
	Automotive	IATF 16949:2016[a]
	Food safety and horticulture	British Retail Consortium (BRC)
		GLOBAL G.A.P.
		FSSC 22000
	Social accountability	SA 8000
		Fairtrade
	Telecommunication	TL 9000
	Occupational health and safety	OHSAS 18000
	Ecolabeling	EU Ecolabel
		Forest Stewardship Council (FSC)
		Marine Stewardship Council (MSC)
		Green Dot

Note: The international standards are listed in the reference section of this module, whereas details regarding the private standards should be obtained from the websites of the relevant certification bodies. AS = Aerospace Standard; EU = European Union; FSSC = Food Safety System Certification; GLOBAL G.A.P. = Global Good Agricultural Practice; HACCP = hazard analysis and critical control points; IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; IT = information technology; OHSAS = Occupational Health and Safety Assessment Series; SA = social accountability; TL = telecommunication.

a. IATF 16949 is the revision of the previous ISO/TS 16949. It is no longer published by the ISO, but by the International Automotive Task Force (IATF). The IATF has created five Oversight Offices (in France, Germany, Italy, the United Kingdom, and the United States) that are responsible for managing the certification scheme.

Most of the standards are clear, in that a single management system certification scheme is operated worldwide, albeit with a multiplicity of certification bodies. Exceptions occur primarily in the food and horticulture sector, where there are a number of standards being used. HACCP was the original standard, and one that has become a regulatory requirement in some markets, such as the EU, Canada, South Africa, and the United States. The principles of HACCP have been codified in a Codex Alimentarius Commission (CAC) international recommendation that has been adopted as a national standard for regulatory purposes in many countries ("CAC/RCP 1:1969—General Principles of Food Hygiene"). The principles are also included in the international standard ISO 22000 ("Food Safety Management Systems—Requirements for Any Organization in the Food Chain").

Retail organizations in Europe and the United Kingdom developed their extended versions of food safety standards, such as the Global Good Agricultural Practice (GLOBAL G.A.P.) and British Retail Council (BRC) private standards, respectively. These came about as retail organizations wished to have more specific requirements than the EU directives to certify the integrity of their suppliers. These two were not the only ones, and the proliferation has taken its toll on compliance and transaction costs. Hence the chief executive officers (CEOs) of a number of the main retail organizations in Europe have pleaded for a more standardized approach in food safety system certification, and the Global Food Safety Initiative (GFSI) came into being. The GFSI does not certify but rather benchmarks various food safety certification schemes to determine which ones the GFSI and the European retail organizations will recognize, thereby cutting down on multiple certification of their suppliers collectively.

Some of the private standards eventually initiate development of international standards. A good example is SA8000 ("Social Accountability 8000: International Standard"), which was developed in 1997 by Social Accountability International and used quite extensively for certification purposes. The ISO developed a pendant to SA 8000 and published ISO 26000 ("Guidance on Social Responsibility") in 2010 after an intense worldwide campaign to get it started. ISO 26000, however, is not a management system–type standard and should not be used for certification purposes; it is only a guidance document. Hence, SA 8000 remains as one of the management system certification standards in this regard.

A similar development awaits the OHSAS 18000 series ("Occupational Health and Safety Management"), which was developed in 1999 by a consortium of NSBs, with the British Standards Institution (BSI) holding the secretariat as a private standard after ISO members could not agree on developing an international standard for occupational health and safety. The success of the OHSAS 18000 series as a management system standard used for certification as well as the growing concern regarding safety in the workplace worldwide has brought about a change in thinking among ISO members, and the ISO 45001 standard ("Occupational Health and Safety Management Systems—Requirements with Guidance for Use") was approved in 2018. ISO 45001 is replacing the OHSAS 18000 series, and companies already certified under OHSAS 18001 have been given three years to comply with the new ISO 45001.

6.5.2 The certification process

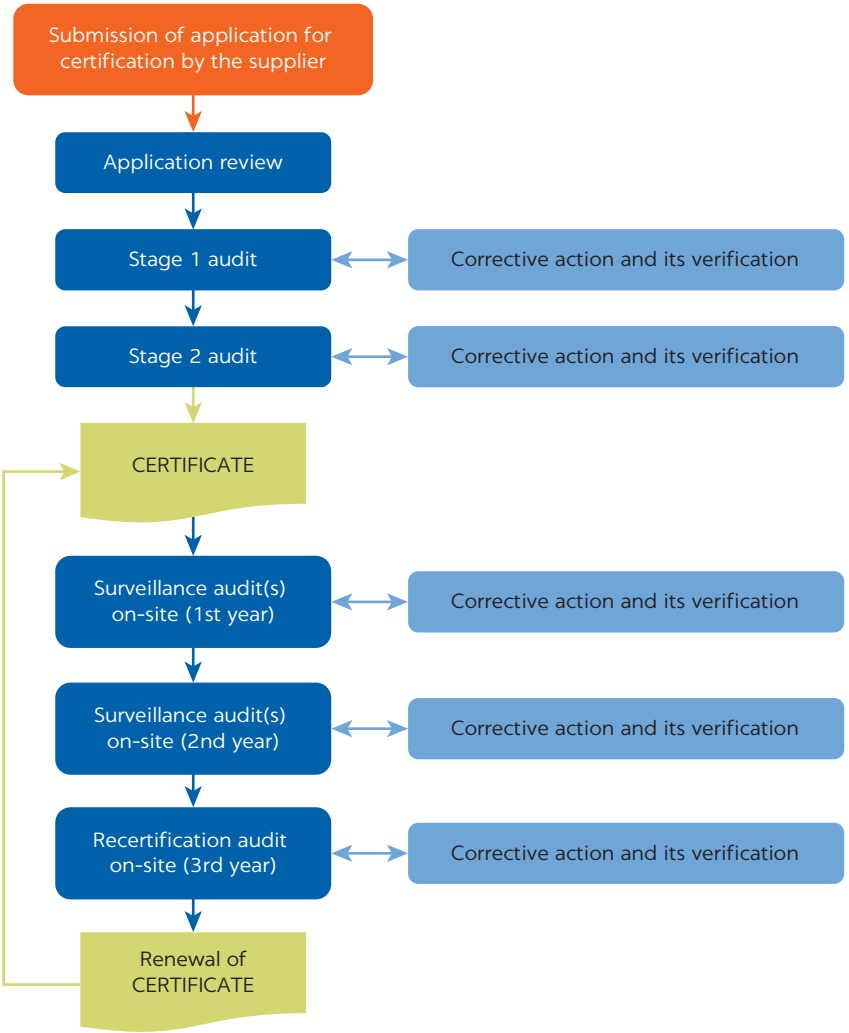
The approach and processes that certification bodies follow to certify a company have been harmonized to a great extent and generally follow the structure as

defined in ISO/IEC 17021-1 (Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems"). Small variations may occur when other standards are used to accredit the certification body, but the fundamentals will remain the same. The process consists of the following steps (figure 6.4):

- *Application:* Application forms must be completed and specified information on the company and its operations provided for the certification body to determine the scope of certification and appoint a team leader for the audit.
- *Stage 1 audit:* The certification body evaluates the quality management system documentation of the applicant to determine whether to proceed to the Stage 2 audit.
- *Stage 2 audit:* The team leader assembles a team of auditors and experts concomitant with the scope of certification and the complexity and size of the operation. The team evaluates the implementation and effectiveness of the quality management system on-site and prepares a final report after nonconformities have been cleared.

FIGURE 6.4

Schematic of the system certification process



Source: Adapted from ITC 2011. ©International Trade Centre. Reproduced with permission, further permission required for reuse.

- *Certification:* Authorized persons, or a committee totally independent of the audit team, review the audit report and decide whether to grant certification. Certification documentation is issued to the applicant if the decision is positive.
- *Surveillance audits:* After certification, the certification body conducts surveillance audits at defined intervals, usually once or twice a year, for two years to determine the continued compliance of the certified company with stated requirements. The surveillance audits are not as comprehensive as the stage 2 audit.
- *Recertification audit:* In the third year after certification, the certification body conducts a recertification audit similar to the stage 2 audit to renew the certificate for another three years, and the cycle repeats itself.

Details of certified companies, together with their scope of certification, are made public on the certification body's website. Failure to deal with identified nonconformities can ultimately lead to the withdrawal of the certificate, or the company can decide not to continue with certification, in which case the certificate is withdrawn as well.

6.5.3 Value of management system certification

Management system certification is resource-intensive to implement and to maintain over and above the certification costs. It is especially the SME sector that frequently battles to obtain certification in the first place and then to maintain it. Hence, the value of management system certification has to be a clear business proposition for the company seeking it. A number of factors need to be considered in this regard:

- *Market entry.* Management system certification is seen as a minimum requirement to enter specific markets. It is often ISO 9001 certification that opens doors for trade. Certification to ISO 9001 ("Quality Management Systems—Requirements") does not guarantee business, but without it a company may have a more difficult time convincing potential customers that it can deliver high-quality products consistently, especially in markets where it is not well known.
- *Regulatory compliance.* Management system certification has found its way into the regulatory domain, with compliance with ISO 9001, HACCP, and other standards frequently demanded by the regulatory authorities to help ensure the integrity of products influencing the health and safety of people, the environment, and the fauna and flora of the country.
- *Competitive advantage.* Some of the private sector management system certifications are a necessity for companies wishing to be competitive in sophisticated markets. Typical examples are
    - *The EU food and horticulture sectors,* where the BRC, GLOBAL G.A.P., or Food Safety System Certification (FSSC) 22000 certification is an imperative if the company wishes to trade with the major retail organizations;
    - *The automotive sector,* where certification to IATF 16949 is a prerequisite to supply components to the major automotive companies; and
    - *Certification to socioeconomic standards,* such as Forest Stewardship Council (FSC), Fairtrade, and other standards in countries with a high level of consumer activism.
- *Improvement incentives.* The implementation of a formal quality management system helps the organization to streamline its production, reduce the

incidence of nonconforming products, make product quality more consistent, and lower inspection costs. The certificate, as a formal demonstration of the implementation of such a system, is an additional bonus.

6.6 IMPACTS OF CONFORMITY ASSESSMENT

The impact of conformity assessment on trade is immense, and this will increase as technology becomes more sophisticated and consumers more discerning. Furthermore, the manufacturing global value chains stretching over many countries demand the seamless integration of components and subassemblies into the final products. This requires a continuous demonstration of compliance with standards and specifications.

6.6.1 Conformity assurance challenges for export businesses

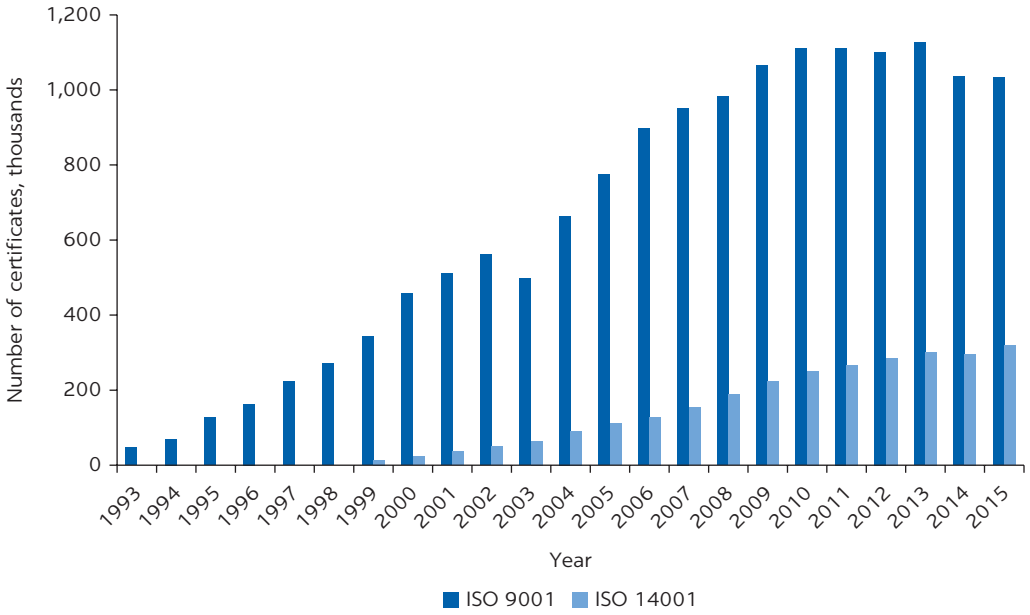
A recent survey by the International Trade Centre (ITC) conducted in 23 countries with a sample of over 11,500 companies revealed the major impact that conformity assessment requirements in sophisticated markets have on smaller companies in low- and middle-income economies that wish to export (ITC 2015). Some of the major findings point to the highly uneven impact that nontariff measures (NTMs) (including import quotas, licensing, rules of origin, content requirements, labeling, testing, and certification) have on companies and countries. Some of the conformity assessment-related challenges include the following:

- *Small companies are most affected.* Up to half of the firms, depending on their size, are affected by NTMs. Those most affected are small companies (over 50 percent), which have less capacity to overcome fixed or variable export costs.
- *Private sector concerns with NTMs are not limited to the strictness of regulations, but often relate to local procedures that present obstacles to trade.* Contrary to the common perception that nontariff barriers are faced in the destination market, the survey revealed that 25 percent of the challenges relate to measures applied by the home country of the exporting businesses, such as export quality inspections.
- *High-income countries are difficult markets for agriculture, and regional markets are difficult for manufacturing.* For agricultural products, high-income countries are perceived as comparatively more NTM-restrictive than other markets. The opposite is the case for manufactured products. This may be due to the integration of exporters from low- and middle-income countries in the industrial global value chains.
- *Conformity assessment in the agricultural sector is one of the key challenges.* Companies in the agrifood sector are particularly affected by sanitary and phytosanitary (SPS) regulations; 48 percent reported trade obstacles in the form of certification or quality control.

6.6.2 Management system certification

Since its first publication in 1987, ISO 9001—the international standard for quality management systems—has had a major impact on businesses. The international standard for environmental management, ISO 14001, has shown a similar pattern, even though its growth has not been as marked as that of ISO 9001 certification.

FIGURE 6.5
ISO 9001 and ISO 14001 certifications, 1993–2015



Source: International Organization for Standardization (ISO) annual surveys (https://www.iso.org/the-iso-survey.html).
Note: ISO 9001 = "Quality Management Systems—Requirements"; ISO 14001 = "Environmental Management Systems—Requirements with Guidance for Use."

The growth of ISO 9001 certifications has been monitored by the ISO over the years (figure 6.5). The "dips" in the growth pattern generally coincide with the publication of revised ISO 9001 standards, after which many companies do not update their quality management systems to the new requirements and hence lose their certification or voluntarily relinquish it. An additional reason may also be that ISO 9001 is considered too generic by businesses using management system certification as a qualification criterion for their suppliers, and they are therefore turning to sector-specific management standards containing sector-specific requirements, many of which are private standards marketed aggressively by their certification bodies. The developments regarding the latest revision of ISO 9001, which includes even more stringent risk assessment requirements, will be interesting to watch.

ISO 14001 certification has made steady gains over the past decade (figure 6.5), but its growth is nowhere near that of ISO 9001 before 2010. ISO 14001 has also been revised recently, and whether certification will continue its steady pace with added requirements—such as the increased prominence of environmental management within the organization's strategic planning and the focus on continuous improvement of its environmental performance—will be decided by the markets.

6.6.3 Certification to private standards as a differentiator of competitors

Standards are essential to trade and play a key role in facilitating economic activities between anonymous agents. In reducing uncertainty, standards are instruments to manage risk, to provide credibility, and to build trust. Standards also

make exchanges more efficient by simplifying transactions, guaranteeing a minimum quality, and allowing for a certain level of predictability. But the role of standards in trade has changed to also being an instrument for product differentiation and market segmentation—that is, differentiation between competitors.

The Organisation for Economic Co-operation and Development (OECD) notes that the relations between the public and private sectors in the establishment and development of food quality standards—of the public, consensus-driven types versus the private sector organization-specific types (see module 3: Standards, section 3.3)—are becoming increasingly complex as the numbers of both types of standards proliferate and become generally more stringent and varied in their applications in both national and international food markets (ITC 2011).

According to the GFSI, certification to private standards—mostly on food safety and quality—accounted for about 22 percent of total retail food sales in 2010. Food safety and quality standards are less prevalent in traditional commodities (for example, grains, sugar, coffee, cocoa, and tea), where traceability standards and labeling initiatives play a more important role. In forestry, the certified forest area amounts to 18 percent of total forest covered by a management plan and 9 percent of global forest coverage (ITC 2015).

Particularly in the food sector, firms use private standards to differentiate themselves from competitors, to build brand recognition and consumer loyalty, and to define and occupy market niches. This leads to companies establishing standards beyond public requirements for food safety. Examples of such private schemes include Tesco Nature's Choice, Filière Agriculture Raisonnée by Auchan, or Carrefour's Filière de Qualité. This development has challenging implications for producers and exporters. Many private standards exceed the requirements of public standards, and hence are more difficult to comply with. One result is that private food standards tend to impose the same requirements on suppliers all over the world, where they face very different preconditions in meeting them (ITC 2015).

6.7 RECOGNITION CRITERIA AND CHALLENGES, INTERNATIONAL AND LOCAL

In general, the acceptance of product certification based on national product certification schemes is still limited to the country of residence of the certification body, even though a number of multinational product certification schemes have begun to change this situation. There are also some product certification schemes that have spread across borders within common markets because of the freedom of movement of products. The situation regarding management system certification is more favorable; for example, ISO 9001 and ISO 14001 certificates from accredited certification bodies are more readily accepted in foreign markets. On the other hand, the situation is quite diffuse for products falling within the scope of technical regulations, where requirements include the certification of management systems to support the quality of the products.

6.7.1 Accreditation at home

In the past, inspection, testing, and certification, especially in the regulatory domain, was the sole purview of government bodies. Their competency may have been contentious, but it was not open for discussion because their authority

was protected by law. This has changed quite dramatically in high-income economies, and these changes are spilling over into low- and middle-income economies as they endeavor to increase their exports to high-income countries. The competency of conformity assessment service providers now has to be demonstrated (such as through accreditation), whether they are public entities or not.

These changes have come about as the state and its organs are extracting themselves from service delivery and are concentrating more on policy and policy implementation. The private sector inevitably has been the "winner" regarding the provision of such conformity assessment services in the regulatory domain. But the private sector conformity assessment bodies must now demonstrate their technical competency, because they do not have the privilege of being considered the ultimate authority by law.

The same tendencies can be observed in the nonregulatory domain, where purchasers of conformity assessment services wish to have assurance that the services for which they contract are indeed technically competent. Hence, in many countries, accreditation has become the common yardstick to determine the technical competency of conformity assessment service providers in both the public and private sectors (as discussed in module 5: Accreditation, section 5.3).

6.7.2 Accreditation across borders

Accreditation bodies have been working hard toward the universal acceptance of inspection and test reports and certification from accredited organizations. This has resulted in networks of mutual recognition overseen by the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). These two organizations have established and managed mutual recognition arrangements among their members, whereby each member, having become a signatory to the multilateral recognition arrangement, undertakes to recognize the inspection and test reports and certificates issued by another party in the system as being equal to the one issued by itself, even in the regulatory domain.

This is generally the case in Europe, Australia, New Zealand, and South Africa. In contrast, in China, India, and the United States, the acceptance of test results and certificates is not yet fully implemented, and designated laboratories and certification bodies are still very much the norm in the regulatory domain. On the other hand, for products outside the regulatory domain, acceptance of test results and certificates from internationally accredited service providers is increasing in most countries (ITC 2015).

In the most widely accepted recognition systems, conformity assessment bodies are accredited to the relevant international standard by the national or regional accreditation body—ISO/IEC 17020 (for inspection bodies), ISO/IEC 17021-1 (for management system certification bodies), ISO/IEC 17025 (for testing laboratories), and ISO/IEC 17065 (for product certification bodies)—as also discussed in module 5: Accreditation, section 5.2, on international standards in accreditation. If the national or regional accreditation body is a signatory to the relevant ILAC or IAF multilateral recognition arrangements, then the output of the accredited conformity assessment service provider stands a good chance of being accepted in other countries.

Private sector certification schemes, on the other hand, frequently operate their own "accreditation" systems for certification bodies, although they are based on the same principles as the international standards listed above.

These include the SA 8000, IATF 16949, and GLOBAL G.A.P., and BRC certification schemes, for example. For some private sector certification schemes, no certification bodies other than the proprietary certification bodies are entitled to certify companies—for example, Fairtrade, Worldwide Responsible Accredited Production (WRAP), and the Forest Stewardship Council (FSC).

This proliferation of accreditation schemes and mutual recognition arrangements is not likely to end anytime soon because of the immense financial returns that are still considered to be advantageously locked up in the various systems. A truly universal recognition system is therefore unlikely even in the medium to long term.

6.7.3 Mutual recognition agreements

During negotiations between countries or trading blocs, recognition arrangements or agreements on the mutual acceptance of certification schemes, especially for regulatory purposes, are sometimes signed or ensconced in the regional common market legislative instruments. One such example is the mutual recognition of national product certification marks among the members of the East African Community (EAC). But even so, this recognition is tempered by the required demonstration of competency through accreditation or peer reviews.

Another, more international system is the recognition arrangement—referred to as "WP.29"—managed by the United Nations Economic Commission for Europe (UNECE) World Forum for Harmonization of Vehicle Regulations. Contracting parties to its 1958 Agreement subscribe to the reciprocal acceptance of approvals of vehicle systems, parts, and equipment issued by other contracting parties.

6.7.4 Recognition among certification organizations

It is possible to establish recognition arrangements between certification organizations on a contractual basis but on a higher level than subcontracting. This comes about when a certification body in a high-income country, for example, accepts inspection certificates, test reports, and even product certification from a certification body in another country, even a low- or middle-income country, as adequate evidence of product compliance to issue its own product certification for its domestic market. The basis for such recognition varies, but is always based on the demonstration of competence between the two partners. This could entail accreditation by an accreditation body or mutual reviews by the partners.

The advantage of such recognition arrangements is that the more senior partner in the agreement obtains a "presence" in the junior partner's country without having to establish its own offices. The surveillance on the certified company is then much more effective, and the cost of surveillance activities is lower, also benefiting the supplier. For smaller certification bodies in low- and middle-income countries, this could be a lucrative model financially when recognized by one of the major certification bodies in a high-income country.

6.8 PUBLIC VERSUS PRIVATE SECTOR SERVICE PROVIDERS

During the developmental phases of a national QI, the state largely has to provide for the establishment of conformity assessment service providers.

The private sector will invest in such services only if a market exists for such services, which is not the case at the beginning. Investments in testing laboratories can run into the millions of dollars before a viable market is established. Once a market has developed, it is quite obvious that the private sector, sensing that there are profits to be made in providing conformity assessment services, would like to establish profitable conformity assessment service providers. This frequently leads to tensions between the public and private sectors.

6.8.1 Public sector service providers

Public sector service providers have the advantage that they seldom have to repay the investments for their establishment; nor do they have investors who wish to see large profits as a payback for their investment. On the other hand, they are often then required by the state to provide conformity assessment services far below market prices to support the SME sector as a political necessity. This approach puts a strain on their finances and is a negative regarding their future financial sustainability. It also distorts the market and creates barriers for private sector service providers to be established. The SME sector needs support, but demanding below-cost services from the public sector service providers is not an appropriate strategy. Direct financial and technical support for the SMEs, properly structured, is a better approach.

On the other hand, public sector service providers can provide lower-cost services to the SME sector, even if they are just covering costs, because they do not operate with a profit motive. In addition, operating without a profit motive allows public sector operators to provide services to rural or sparsely populated areas with little prejudice. As long as there is no private sector competition, everything works fine. However, once private sector service providers are established, they usually can adapt much more quickly to market realities and changes, and in this way, take market share from the public sector operators.

The real challenge surfaces when conformity assessment services for the regulatory domain are liberalized, and public sector operators lose their legal or perceived monopoly to provide such services. The public service operators are incensed and will fight to the bitter end not to lose this monopoly. The government will have to take a clear and unambiguous stand in this matter; otherwise, the country will be the loser in the end.

As for acceptance in the local marketplace, the public sector operators sometimes have the advantage because they are the "government." This is not a universal truth, and the opposite also happens, especially if service delivery is not good. Where public sector operators have a real challenge is gaining acceptance in foreign markets or for the testing and certifying of products to be exported to lucrative markets such as the EU, the United States, and others. In this case, the dominant market position of the multinational conformity assessment service providers in the foreign markets (such as the various TÜV companies, SGS S.A., Bureau Veritas S.A., and others) is a very hard nut to crack.

This situation is exacerbated by policies such as that in the EU, whereby only conformity assessment service providers resident in Europe are designated as "notified bodies" for the testing and certification of products falling within the scope of technical regulations. These policies exclude public sector conformity assessment bodies from low- and middle-income countries and raise the cost of compliance for exporters in such countries, unless the country reach a mutual recognition agreement with the EU. There are few of those, however.

6.8.2 Private sector service providers

Private sector conformity assessment service providers start to be established once a viable market for their services has developed. The policy of the government also has to favor the establishment of private sector operators by liberalizing the conformity assessment service regimes for the implementation of technical regulations rather than limiting such services to a public sector entity. In high-income economies and increasingly also in many low- and middle-income economies, this is the case; the state and its agencies are slowly disengaging from service delivery, concentrating on policy and the implementation of the law.

Generally speaking, private sector operators are also more flexible in adapting to changing market situations, and market forces to some extent ensure that service quality remains high. If the laboratory or certification body does not provide good service, and if there is a choice, customers will go elsewhere. The difficulty in smaller economies is that there is usually not a great choice because of the high levels of investment required to establish speciality laboratories. The technical competency of private sector service providers, just like public sector service providers, should be demonstrated through accreditation.

A significant challenge regarding certification schemes based on private standards is that they frequently operate as a closed shop with respect to certification bodies—that is, only certification bodies that are part of the organization publishing the standard are mandated to provide certification services. In low- and middle-income countries, this may mean that a certification body from abroad must be used, with the much higher costs that this entails. In some cases, it may be possible to establish a certification body at the national level for private standard certification schemes, or a national certification body may be contracted to conduct the audits with the parent body still issuing the certificate, but this would depend on their business model. In all of these cases, the parent body usually conducts a form of accreditation.

A related challenge for low- and middle-income countries regarding service delivery by private sector operators is that the SME sector is often neglected. SMEs frequently do not have the finances to pay for private sector conformity assessment services, and they are often based in rural or sparsely populated areas. Both factors militate against the provision of services that are based on a profit motive. In such cases, the government and its agencies may have to continue to provide conformity assessment services at affordable prices for the SME sector. Such a division of labor can work, but there needs to be a good understanding between the government, its agencies, and the private sector for it to be successful.

6.9 INTERNATIONAL CERTIFICATION SCHEMES

Over the years, several large conformity assessment bodies have established themselves by providing inspection, testing, and certification services in many countries. They are the *multinational* organizations in the conformity assessment service domain, even though they are sometimes touted as *international* organizations, which they are not. There are, however, a few international organizations that manage international conformity assessment schemes. Three of them are discussed below.

6.9.1 International Electrotechnical Commission (IEC)

The IEC, unlike its counterparts the ISO and the International Telecommunication Union (ITU), operates international certification schemes for four various types of electrical and electronic products:

- *IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE):* The IECEE schemes address the safety, quality, efficiency, and overall performance of components, devices, and equipment for homes, offices, workshops, and health facilities, among others. In all, the IECEE covers 23 categories of electrical and electronic equipment and testing services.
- *IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx):* The IECEx schemes address the safety and performance of equipment destined for use in hazardous locations or explosive atmospheres—that is, areas where flammable liquids, vapors, gases, or combustible dusts are likely to occur in quantities sufficient to cause a fire or explosion.
- *IEC Quality Assessment System for Electronic Components (IECQ):* The IECQ scheme is an approval and certification system covering the supply of electronic components and associated materials and assemblies (including modules) and processes. It includes both a product and a facility certification scheme.
- *IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications (IECRE):* The IECRE scheme is an approval and certification scheme relating to equipment for use in renewable energy applications, including the safety thereof.

The schemes are based on the principle of mutual recognition (reciprocal acceptance) by scheme members of test results and factory audits carried out for the purpose of obtaining certification or approval at the national level. Products or factories are inspected, tested, and audited as relevant against IEC standards and under the auspices of a member of the relevant IEC scheme, referred to as a national certification body (NCB). The NCB designates the laboratory to be used. The list of recognized NCBs is posted on the relevant scheme's website.

A manufacturer is then entitled to take the test and audit results to an NCB in another country, and the NCB in that country will issue the certification in that country as required by the marketplace or the regulatory authorities. In the case of the IECEx scheme, the manufacturer is licensed to affix the IECEx conformity mark on the product, which is recognized by the other member countries of the scheme as evidence that the product complies with the relevant IEC standard. Equipment used in explosive atmospheres is subject to technical regulations in most countries, and these regulations are often based on IEC standards.

6.9.2 International Organization for Legal Metrology (OIML)

The International Organization for Legal Metrology (OIML) operates two international conformity assessment schemes: the OIML Basic Certificate System and the OIML Mutual Acceptance Arrangement (MAA). The aims of the OIML conformity assessment schemes are to

- Foster mutual confidence among participating OIML member states and corresponding members in the results of type evaluations that indicate conformity of measuring instruments;

- Promote the global harmonization, uniform interpretation, and implementation of legal metrological requirements for measuring instruments; and
- Promote efficiency in time and cost of national type evaluations and approvals, or recognition of measuring instruments under legal metrology control in support of facilitating global trade of individual instruments.

The OIML Basic Certificate System for measuring instruments enables manufacturers to obtain an OIML Basic Certificate and an OIML Basic Evaluation Report indicating that a given measuring instrument type complies with the requirements of the relevant OIML international recommendation. Certificates are issued by OIML member states that have established one or several Issuing Authorities responsible for processing applications from manufacturers wishing to have their measuring instrument types certified. The OIML Issuing Authorities must demonstrate compliance with ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services") using the results of testing laboratories that comply with ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories").

These certificates may be accepted by national legal metrology authorities on a voluntary basis, thereby simplifying the type approval process for manufacturers and legal metrology authorities by eliminating expensive duplication of test procedures. The Basic Certificate System offers a viable and trustworthy alternative to countries where relevant test facilities are not available.

In addition to the Basic Certificate System, OIML has also developed a Mutual Acceptance Arrangement (MAA). Within the OIML MAA, confidence in test and examination results is reinforced by a formal and mandatory peer evaluation process. This process verifies the compliance of the OIML Issuing Authorities and the testing laboratories with the respective standards and also the capability of the testing laboratories to perform the tests. To prove this compliance, the Issuing Authorities and the testing laboratories must be accredited for the field covered by the respective OIML Recommendations or undergo peer assessment.

6.9.3 UNECE World Forum for Harmonization of Vehicle Regulations

The UNECE World Forum for Harmonization of Vehicle Regulations—commonly referred to as Working Party 29 (WP.29)—currently has the leading role in the global harmonization of automotive safety regulations. It is responsible for the implementation of two major agreements reached by the participating countries, known for short as the 1958 Agreement and the 1998 Global Agreement.

The UNECE 1958 Agreement provides for the mutual recognition of governmental certifications based on the Economic Commission for Europe (ECE) Regulations (approximately 135 at the time of this writing), while the purpose of the 1998 Global Agreement is to harmonize automotive transportation-related regulations globally. Mutual recognition is not part of the 1998 Global Agreement; its focus is limited to the adoption of agreed-on Global Technical Regulations for vehicles by contracting parties. The ECE Regulations—now called UN Regulations under the 1958 Agreement and the UN Global Technical Regulations under the 1998 Global Agreement—are both developed and discussed within UNECE WP.29.

The mutual recognition of approvals provided under the 1958 Agreement aims to facilitate the international trade in vehicles and their components. If a component type is approved according to a UNECE Regulation by any of the

contracting parties to the 1958 Agreement, all other contracting parties that have signed the Regulation will recognize this approval. This avoids repetitive testing and approval of components in the various countries to which the components are exported. It also helps to reduce the time and resources devoted to design, manufacturing, and approval as well as the entering into service of vehicles and their components.

Around 50 countries are contracting parties to the 1958 Agreement, the most notable exceptions being Canada and the United States, which have a different approach to vehicle component certification than countries operating a formal approval thereof by regulatory authorities. Approved components are typically marked with a capital "E" within a circle also containing the number assigned under the 1958 Agreement to the approving country. Roughly the same number of countries are contracting parties to the 1998 Global Agreement, but the number of UN Global Technical Regulations is still much lower than the UN Regulations under the 1958 Agreement, about 15 at the time of this writing.

6.10 CONFORMITY ASSESSMENT SERVICES AND THE SME SECTOR

One of the major challenges for SMEs seeking to enter the more sophisticated markets and integrate into global value chains is obtaining the relevant inspection and test reports and certification that demonstrate product or component compliance with stated requirements. This is important in the low- and middle-income country context because SMEs often make up the bulk of those countries' industrial base. It is, however, easier said than done. SMEs—over and above all the other challenges, such as financing, management capacity, and product or service design—find it difficult to implement the appropriate manufacturing controls, never mind the more sophisticated quality assurance systems required for ISO 9001 certification, for example. The same applies to obtaining appropriate positive test reports from accredited testing laboratories.

Many governments of low- and middle-income economies, in implementing industrialization or export policies, will try to support the SME sector in this regard. A number of strategies are available:

a. *Providing training and consultancy services* to SMEs in specific sectors that are important to the economy. Such schemes are frequently supported by the donor community in technical development projects.
b. *Forcing public sector conformity assessment bodies to provide inspection, testing, and certification services* for the SME sector at below-market related prices, sometimes even below cost.
c. *Providing financial support to SMEs* to gain the relevant management system or product certification.
d. *Affording preferential treatment* to SMEs in state purchases if they are certified.

Of the three possibilities, (b) is the most inappropriate strategy to follow. In this case, the public sector conformity assessment body will have to be subsidized by somebody, usually the government or sometimes the development partners in an indirect way. This approach compromises the financial sustainability of the conformity assessment body, distorts the market, and acts as a barrier for private sector conformity assessment bodies to be established.

Strategy (c) has a good chance of having a lasting impact if it is designed in an appropriate way. Countries that have achieved notable success in this regard would refund part of the testing or certification fees (usually around 50 percent) after the SME has obtained certification, and then would refund a further percentage (usually around 25 percent) after three years if the SME has successfully maintained its certification. Schemes that refund 100 percent or close to it after successful certification seldom make a lasting impact because the SMEs frequently drop the certification once they have been refunded.

Among the support systems under strategy (a) that have had a fair amount of success are systems whereby SMEs are given a small percentage of government or large company contracts to supply mundane products or consumables, such as toilet paper, school furniture, grass cutting machetes, and so on. The government or large company will at the same time contract the NSB, insofar as it has the capacity to do so, to help the SMEs set up appropriate manufacturing controls and to conduct the final inspection on a batch-by-batch basis for the products in question. After a while, the SME will have developed to the point where such support is no longer necessary.

6.11 THE CERTIFICATION CHOICE FROM THE SUPPLIER'S PERSPECTIVE

With the tremendous number of product and system certifications on offer, an economic operator has a difficult choice. All of these schemes have a cost, hence the choice needs to make good business sense. In general, the choice of a certification scheme will depend on the answers to the following questions (ITC 2011):

- Is a product certification scheme relevant, or should it be a management system certification scheme?
- If the choice is a product certification scheme, is one offered by a multinational certification body the right choice, or would a national one be more appropriate and sufficient to serve the purpose in the short and long terms?
- Is a more general management system certification required, or would a sector-specific scheme be more appropriate?
- If a general management system certification scheme is chosen, would it be focusing on quality, the environment, information security, or a combination of these?
- If a sector-specific certification scheme is necessary, in which sector should it be; for example, automotive parts, medical devices, software development, and so on?
- Is the cost of implementing the necessary controls and systems, plus initiating and maintaining the certification, worthwhile relative to the advantage gained in the marketplace?

Selecting the most appropriate certification scheme and certification body should ensure a valuable long-term partnership. A structured approach to the selection process is therefore essential. Some of the key issues that may help the selection process are described below.

6.11.1 Product certification scheme selection

Some product certification marks have gained a predominant position in the marketplace, and products carrying these marks are recognized as good value for money

or as high-quality products by purchasers. This is especially true in the home markets of major product certification bodies in both high-income and low- and middle-income countries, and less so in their markets abroad. It is therefore important to obtain relevant information in this regard, because the appropriate product certification marks can be invaluable in gaining market share where the market does not yet recognize the brand names of the products. This holds true for both local and imported products and is relevant in the case of government purchases where a product certification mark could be an advantage in the tender process.

If the product to be marketed falls within the scope of a technical regulation, it is useful to determine whether product certification would be considered a demonstration of compliance acceptable to the regulatory authorities. This acceptability could depend on accreditation of the product certification body, on its designation by the regulatory authority, on a unilateral recognition as "deemed to satisfy" evidence, and other considerations. The international schemes offered by the IEC and OIML, for example, may be interesting in this respect as well (see section 6.9 on international certification schemes). As is the case for market acceptance, obtaining reliable information in this respect could be invaluable in lowering the overall cost of compliance with the relevant technical regulation.

Product certification schemes vary tremendously in how they are financed. In some cases, there is an annual fee based on actual production that will carry the product certification mark; this fee covers all surveillance audits and post-award testing activities. In other schemes, these are paid for separately. Some have a base charge independent of production combined with an additional fee based on the production figures. Others include costs for each surveillance audit, interim testing of mark-bearing products, recertification fees, and so on. These costs have to be determined and factored into the production costs to decide whether it makes good business sense to obtain the relevant product certification; that is, whether the potential growth in sales warrant the product certification costs.

6.11.2 Management system certification scheme selection

General management system certification schemes as well as sector-specific schemes abound. The choices are immense. The most pertinent question that should be asked relates to the purpose of the management system scheme envisaged. Table 6.4 provides guidance on some of the better-known schemes, even though it is nowhere near comprehensive. Specific situations may require totally different schemes, especially when considering sector-specific schemes (of which there are far too many to list here).

As is the case for product certification, the costs of management system certification can vary quite a bit, depending on the business model of the certification body. Annual certification fees, audit fees, auditor costs, and recertification fees need to be factored into the decision making, and the most cost-effective and beneficial ones for the company to be certified should be selected.

6.11.3 Certification body competency and focus

It is important to select not only the appropriate certification scheme, but also the most relevant certification body. Questions that need to be asked and

TABLE 6.4 Selection criteria for management system certification schemes

PURPOSE OF IMPLEMENTATION	RELEVANT STANDARD
Generic management system certification	
To obtain customer satisfaction by consistently providing conforming products or services	ISO 9001
To ensure the security of the company's valued information and create confidence among customers in the security of information they provide	ISO/IEC 27001
To demonstrate to stakeholders that the company is environmentally responsible	ISO 14001
To provide a safe workplace for employees by managing occupational health and safety risks in the workplace	OHSAS 8000
To ensure employees' welfare and demonstrate compliance with social accountability policies, procedures, and practices to interested parties	SA 8000
To improve energy performance, including energy efficiency, energy use, and consumption	ISO 50001
Sector-specific management system certification (see also table 6.3)	
To become a reliable supplier of automobile production materials, parts, and services meeting OEM requirements	IATF 16949
To become a reliable supplier of equipment and materials needed by the petrochemical, oil, and gas industry supply chain	ISO/TS 29001
To become a reliable supplier to companies involved in the design, production, installation, and servicing of medical devices	ISO 13485
To become a reliable supplier in the aviation, space, and defense industry supply chain	AS 9100
To demonstrate the ability to supply products or services to telecommunication service providers and their suppliers	TL 9000
To become a reliable provider of IT services, either within the organization or to external organizations obtaining outsourced services	ISO/IEC 20000
To reduce risks to people and cargo within the supply chain	ISO 28001
To become a reliable supplier of food safe for human consumption, whether of animal or vegetable origin; fresh or processed; perishable or with long shelf life; or with or without additives, vitamins, and biocultures	HACCP ISO 22000 FSSC 22000 BRC GLOBAL G.A.P.
To ensure the safe packaging, storage, and distribution of safe food and consumer products	BRC GLOBAL G.A.P.

Source: ITC 2011.
Note: BRC = British Retail Council; GLOBAL G.A.P. = Global Good Agricultural Practice; HACCP = hazard analysis and critical control points; IT = information technology; OEM = original equipment manufacturer. For full information about each of the listed standards, see the references at the end of the module.

answered in the affirmative regarding the competency of the certification body include the following:

- Is the certification body accredited for the public or private standard to which certification is required?
- Is the accreditation body by which the certification body is accredited a signatory to a multilateral recognition arrangement covering the scope you are interested in, such as those operated by the IAF for public standards, or in the case of private standards, the relevant multinational one?
- Does the accreditation of the certification body cover the scope of the scheme the organization wishes to be certified against, both locally or abroad, as relevant?

Another important selection parameter is whether the certification body is recognized in the marketplace. If the certification body includes well-known names in its list of certified companies, that could be a useful indicator. A certification body that has confidence in its operations will not object to putting

potential clients in touch with certified companies for feedback on its performance. If the certification body is operating in a number of countries, that may also be of interest to potential exporters.

The certification needs of a company may be manifold, either now or in the future. Some certification bodies can provide an integrated service—that is, a system that integrates quality management certification with certification relating to environmental management, and/or health and safety, and/or risk management, and/or even product certification. If this is a desirable feature for the company, such an integrated certification service may be more cost-beneficial than obtaining stand-alone certification for each area. SMEs may find it difficult to obtain and maintain certification. Some certification bodies provide specialized schemes for the SME market, and these may be the obvious choice for SMEs.

NOTES

1. The CE marking (a "CE mark" does not exist) 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. These may involve third-party conformity assessment service providers (that is, notified bodies) depending on the new directive, but the manufacturer or supplier is not licensed by a product certification body or anybody else to affix the CE marking on the product; it is done totally on that manufacturer's or supplier's own responsibility.
2. HACCP is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe. An international guideline is published by the Codex Alimentarius Commission (CAC/RCP 1-1969) that has been adopted as a national standard by many countries.
3. In some countries, management system certification is termed registration, and the certification body a registrar.

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