THE QUALITY INSTITUTIONS
An enabling framework for international trade

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Introduction

With the extension of international sourcing practices and "just-in-time" production and distribution strategies, companies have been forced to address the danger that their entire production lines might be delayed by the delivery of a few bad component parts. As a result, suppliers have had to find ways to ensure that their goods and services are accompanied by the necessary quality assurances. Over small distances, where communication is relatively easy and the possibility of site visits helps to increase confidence in suppliers, this can be done relatively informally. But over long distances, where communication is limited and relationships are weaker, companies have found that formal quality assurances have become increasingly more important for winning supplier contracts and gaining international market access. This has involved a growing list of documented technical and quality management process requirements, and increasingly rigorous conformity assessment requirements.

Over time, a relatively complex institutional structure has developed – at the national, regional and international level – to accommodate the growing focus on quality assurance. This structure is based on the three "quality institutions": rule making (standardization and regulation); conformity assessment; and accreditation. Each of these institutions, which are each made up of a variety of different actors, is vitally important to the functioning of any quality assurance regime. Together, these institutions play an important role in facilitating international trade and investment by enabling producers both to establish what is required of them, and to credibly demonstrate their compliance with a wide variety of quality standards.

As mentioned above, there are three institutions that form the basis of any quality assurance regime:

1. Rule Making, including the development of both mandatory technical regulations and voluntary standards;
2. Conformity Assessment; and
3. Accreditation.

A company needs to understand and have access to each of these institutions if it is to avoid the technical barriers to trade that can often be related to quality assurance requirements. With globalization, the architecture of each of these institutions is increasingly being built at the international level. But without a sound national infrastructure, most countries will find it difficult to participate in the international activities.

RULE-MAKING: STANDARDS AND TECHNICAL REGULATIONS

Standards and technical regulations are documents that clearly identify the commonly accepted guidelines, rules and criteria that help to determine if a product, process or service is suitable for its intended purpose. If they are clearly defined and easily obtained, standards and technical regulations enable companies to communicate quality requirements with their suppliers and customers precisely, consistently and efficiently. Whereas standards are voluntary, technical regulations are mandatory; the WTO's Agreement on Technical Barriers to Trade (TBT Agreement) sets out slightly different requirements for the development of standards and technical regulations.

Most countries have designated national bodies that develop standards and technical regulations, and that also provide other services, such as information on standards and regulations being developed in other countries of importance to the export sector. In general, there is a value in having a limited number of these bodies in order to facilitate coordination, and to reduce the number of competing or overlapping standards or technical regulations. Almost ever country in the world has a designated national standards body (NSB) that is mandated to oversee the development of voluntary standards. In some cases, NSBs are also involved in the development of mandatory technical regulations, or the standards that they develop are used as the basis for technical regulations. Only a government body can formally establish a mandatory technical regulation.

In developed countries, national standards bodies (NSBs) are frequently private organizations with close links to the private sector user-community. In developing countries, NSBs are frequently public bodies with close links to other government agencies, and may be responsible for developing both national standards and technical regulations. The vast majority of standards are developed through NSBs but, increasingly, a host of private, non-governmental organizations are taking the lead in the development of environmental and social standards. To date, no environmental or social standard developed by a private standards body has been adopted as a mandatory technical regulation[2]. Most NSBs also participate in International Standards Bodies (ISBs).

CONFORMITY ASSESSMENT

Conformity Assessment is the process of testing compliance with a standard or technical regulation. Access to conformity assessment services enables companies to demonstrate that they comply with the relevant requirements. Depending on the circumstances, it can be undertaken through a process of independent verification (third-party), peer review (second party), or self-declaration (first party). Depending on the sort of standard or technical regulation, conformity assessment services may be provided by laboratories and testing facilities with specialized metrology equipment, or by management system certification companies.

In developed countries, conformity assessment is generally undertaken by a large number of competing commercial entities. In many developing countries, where the market for conformity assessment is not as large, these services are provided by relatively fewer entities, and are frequently state-sponsored labs and testing facilities.

For technical regulations, conformity assessment is generally undertaken through third-party verification by entities that have been given the mandate to monitor regulatory compliance by a government agency. This is not always a public body. For standards, conformity assessment can either be through first-, second-, or third-party verification[3]. Third-party verification is undertaken by any number of (generally) private companies that have been granted a license in the country in which they wish to operate. Importantly, certifications granted by a conformity assessment body in one country may not necessarily be recognized in other

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[2] It should be noted that, in some cases, governments have adopted policies to encourage the application of environmental or social standards. For example, the Chinese government has integrated the Forest Stewardship Council's (FSC) sustainable forest management standards into its national forest strategy.

[3] First-party verification is provided by the company itself and involves a self-declaration of conformity; second-party verification is generally undertaken by an interested party, such as a corporate customer with a supply contract; third-party verification is undertaken by trained professionals working for independent verification companies.

countries. Thus, companies may sometimes have to obtain multiple certifications if they intend on selling into more than one market.

ACCREDITATION

Accreditation is defined as a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks[4]. When assessing the competence of conformity assessment bodies, accreditation agencies generally assess their competence against procedural guidelines. These guidelines are set, and the assessments are generally undertaken, by national accreditation agencies that are either part of a government agency, or specifically mandated by one. A conformity assessment body cannot operate in a country, or test against a specific standard, unless they have been licensed by the relevant accreditation agency. Although it is not always the case, particularly in developing countries, international best practice recommends a division of responsibility between standardization, certification and accreditation activities.

Because national accreditations are not generally recognized between countries, conformity assessment bodies must seek separate accreditation for each country in which it seeks to do business. Increasingly, however, regional and international frameworks are being developed to promote the mutual recognition of different

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Box 1: International Guidance Documents Relevant to Conformity Assessment and Accreditation*

- ISO/IEC Guide 2: *General terms and their definitions concerning standardization and related activities*: International Organization for Standardization, Geneva.
- ISO/IEC Guide 58: *Calibration and testing laboratory accreditation systems – General requirements for operation and recognition:* International Organization for Standardization, Geneva.
- ISO/IEC Guide 61: *General requirements for assessment and accreditation of certification/registration bodies*: International Organization for Standardization, Geneva.
- ISO/IEC Guide 62: *General requirements for bodies operating assessment and certification/registration of quality systems*: International Organization for Standardization, Geneva.
- ISO/IEC Guide 65: *General requirements for bodies operating product certification systems*: International Organization for Standardization, Geneva.
- ISO/IEC 17010: *General requirements for bodies providing accreditation of inspection bodies*: International Organization for Standardization, Geneva.
- ISO/IEC 17020: *General criteria for the operation of various types of bodies performing inspection:* International Organization for Standardization, Geneva.
- ISO/IEC 17025:1999: *General requirements for the competence of testing and calibration laboratories*.

* List compiled by David Stanger.

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national accreditations. Some private standards and labeling initiatives, such as the International Federation of Organic Agriculture Movements (IFOAM) and the Forest (FSC) and Marine Stewardship Council (MSC), have set up independent accreditation bodies outside of the formal accreditation system in order to maintain control over the quality and supply of certification services for their standards.

THE INTERNATIONAL ARCHITECTURE

Inconsistent or ambiguous rules create a climate of uncertainty that can reduce the efficiency of business decisions. For example, if a technical regulation limiting the

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[4] ISO/IEC Guide 2

emission of carbon changes frequently over time, it is very difficult for a company to conduct accurate cost-benefit analyses when deciding, for example, to purchase cleaner production technology. A high degree of temporal inconsistency in quality requirements is bad for business and can disproportionately raise the costs of compliance.

In the same way, a high degree of geographical inconsistency is also bad for business. It is expensive and complicated for a company to operate multiple production runs to produce goods that need to comply with different quality requirements in each different export market. While international trade provides opportunities for companies to benefit from important economies of scale, a proliferation of different standards and technical regulations can drastically reduce these benefits. In the same way, different guidelines by which conformity assessment or accreditation is conducted can also create barriers to trade. The overall goal of the international quality assurance community is to promote a system whereby products are "once tested, once certified, accepted everywhere". The international harmonization of rule making, conformity assessment and accreditation procedures, is extremely important if a global quality assurance system – be it for product quality assurances or environmental and social quality assurances – is to facilitate trade.

Once Tested: The Harmonization of Rule Making

The most straightforward way to reduce the costs of proliferating standards and technical regulations is to create a single set of rules. Indeed, the TBT Agreement has an explicit bias towards international standards: it requires Members to base all national standards and technical regulations on existing international standards[5], and also encourages Members to participate in the development of international standards[6]. By requiring Members to use international standards as the basis for national rules, be they voluntary or mandatory, the WTO is promoting international harmonization and reducing the costs to business of proliferating standards. Of course, this raises the question of what should be considered an international standard.

Up until recently, an international standard was quite straightforward: an international standard was any document developed through an international standards body (ISB), and an ISB was any international body whose membership was open to all national standard bodies[7]. Most international standards are developed within a select group of formal international standards bodies (ISBs). The most important of these traditional ISBs have specific jurisdictions; thus the International Telecommunications Union is the recognized forum of the development of international standards for telecommunications, and the FAO's Codex Alimentarius Commission is the forum for the development of international food safety standards[8].

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[5] TBT Agreement, Article 2.4; and Annex III, paragraph F.

[6] TBT Agreement, Article 2.6; and Annex III, paragraph G.

[7] It is important to note that international standards are not developed **by** international standards bodies, but rather **through** them: an ISB is simply a rules-based forum that facilitates negotiations between national standards bodies. Thus, ISO and Codex do not develop international standards: their members develop them. ISO and Codex simply oversee the development process and then publish them as international standards.

[8] As recently as 1991, UNIDO estimated that over 85% of all international standards were developed through just 3 ISBs: the ITU, the International Electrotechnical Commission, and the International Organization for Standardization (ISO).

In recent years, however, international trade policy has shifted so that the focus is no longer on the ISB itself, but rather on the process through which international standards are set[9]. This is an important development, because it effectively broadens the number of bodies that can develop international standards recognized under the TBT Agreement, making it more difficult for countries to follow and influence all international standardization activities.

Of course, countries and their national standards body representatives cannot always agree to a common set of requirements. In addition, countries have recognized that two standards that are substantively different can still achieve the same overall objective. So, where international standards cannot be agreed, but where different standards can achieve the same objective, the TBT Agreement recommends that Members consider recognizing each other's standards as technically equivalent. Especially where domestic environmental, social and economic characteristics or technological capacities are different and require slightly different standards, this is, in principle at least, a useful way of reducing the costs of the proliferation of standards and technical regulations.

However, while there is a strong institutional infrastructure for the negotiation of international standards – both in terms of the number of traditional ISBs and in terms of the consensus-based procedures for the development of international standards outside of the ISBs – there is only a limited similarly robust infrastructure for the negotiation of technical equivalence agreements, and this only in the case of sanitary measures associated with food import and export inspections[10]. As a result, and although this is a very important policy tool, particularly in the case of public-policy standards and technical regulations that need to be refined to suite local conditions and priorities, it is rarely used in practice[11].

Once Certified: Harmonization of Conformity Assessment

Different countries often impose different rules for testing compliance, even against the same standard or technical regulation. Therefore, even if a harmonized international standard or technical regulation exists, market access can nonetheless be restricted by a proliferation of conformity assessment procedures, which could require companies seeking access to a variety of different markets to undertake and pay for a variety of different compliance tests.

A variety of bodies develop international standards for conformity assessment, including traditional ISBs, such as ISO's Committee on Conformity Assessment (CASCO); conformity assessment trade associations, such as the International

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[9] This is the case for the TBT Agreement: the guidelines for international standard-setting included in Annex 4 of the Second Triennial Review of the TBT Agreement outline criteria for determining if a standard should be considered international. The SPS Agreement, which addresses a far more limited scope of issue – essentially limited to food safety, lists three bodies that it recognizes as international standards bodies: the FAO's Codex Alimentarius Commission, the OIE, and the 3rd one.

[10] At is meeting of 25 February – 1 March 2001, in Brisbane, Australia, the Codex Committee on Food Import and Export Inspection and Certification Systems published a "Draft Guidelines On The Judgment Of Equivalence Of Sanitary Measures Associated With Food Inspection And Certification Systems", which helps to create a structure for the establishment of equivalence between sanitary measures, which it broadly characterizes as including: infrastructure; programme design, implementation and monitoring; and/or specific requirements. See The Codex Committee on Report Of The Tenth Session Of The Codex Committee On Food Import And Export Inspection And Certification Systems; April 2002, ALINORM 03/30, Appendix III.

[11] For more on the role of an international framework for technical equivalence agreements, please see: Rotherham, Tom: "Market Access, Sustainable Management Standards and Technical Equivalence"; paper prepared for the Global Forum on Trade, Environment and Development, 23-27 June, 2002, Quito, Ecuador.

Laboratory Accreditation Cooperation (ILAC); or UN Agencies, such as the World Health Organization (WHO). In other cases, national conformity assessment procedures, or even procedures promoted by industry associations, can become *de facto* international standards for conformity assessment due to their prevalence in the marketplace.

Where no internationally adopted approach exists, the WTO TBT Agreement requires that Members consider recognizing conformity assessments done according to different procedures, so long as they are deemed equally effective[12]. This process is referred to as "mutual recognition of conformity assessment" and is analogous to the technical equivalence agreements that are negotiated between countries with different product standards and technical regulations.

Whereas there is a limited international institutional framework to support the negotiation of technical equivalence agreements, there is more developed framework for the negotiation of mutual recognition agreements. For example, Annex 5 of the Second Triennial Review of the TBT Agreement contains an "Indicative List Of Approaches To Facilitate Acceptance Of The Results Of Conformity Assessment", which are intended to facilitate the negotiation of mutual recognition agreements between governments[13]. Also, Codex's "Draft Guidelines On The Judgment Of Equivalence Of Sanitary Measures Associated With Food Inspection And Certification Systems" addresses the equivalence of conformity assessment procedures[14].

Accepted Everywhere: Harmonization of Accreditation

Even if there is a single international set of rules (or a technical equivalence agreement in place), and a single internationally accepted set of conformity assessment procedures for testing against that standard or technical regulation (or a mutual recognition agreement in place), it is still possible that a certification issued by a conformity assessment body in one country will not be accepted in another. This is because of the incomplete harmonization of accreditation procedures, and the lack of recognition of different accreditation structures.

As mentioned above, accreditation is the process of determining the competence of bodies that conduct conformity assessments, and is usually undertaken by a single accreditation agency in each country. A certificate of compliance with a standard or technical regulation will only be accepted if the company that has undertaken the conformity assessment is accredited, or registered, by the national accreditation agency. Therefore, if a quality assurance is required to access a particular market, the actual certificate of assurance often may have to be granted by a company that is registered by the domestic accreditation agency. This can result in increased costs for exporters, who must import conformity assessment services from the country to which they intend to export goods.

Over the course of the last 5 years, efforts have been made to harmonize the accreditation process. In particular, this includes the multilateral recognition arrangement (MLA) framework developed by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC)[15]. Signatories to the IAF-ILAC MLA are obliged to recognize any conformity assessor

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[12] TBT Agreement, Article 6.1

[13] WTO/G/TBT/9, 13 November 2000: "Second Triennial Review Of The Operation And Implementation Of The Agreement On Technical Barriers To Trade".

[14] Report Of The Tenth Session Of The Codex Committee On Food Import And Export Inspection And Certification Systems; April 2002, ALINORM 03/30, Appendix III.

[15] For more information see: www.iaf.nu; www.ilac.org

that is accredited by any of the other signatories and, therefore, to accept conformity assessments provided by those companies. In return, signatories are given the right to periodically inspect each other's national accreditation system in order to ensure its ongoing competence and effectiveness. The MLA structure was initially developed by the IAF only in the context of accreditations for companies that provide management system certification services. However, with the cooperation of ILAC, this framework is now being extended to also cover companies that provide product certification services as well.

The IAF-ILAC framework is perhaps the most important development in quality assurance harmonization in the last decade. This paper will focus on the role of ILAC and IAF in promoting international trade through the establishment of an international framework for the mutual recognition of national accreditations.