C INSTITUTIONS AND POLICY ISSUES

This Section explains how standardization and conformity assessment work in practice and describes the relevant characteristics of standardization and conformity assessment infrastructures in various regions of the world. It starts with a discussion of the standardization process and considers where standardization takes place, how it is organized and who participates in the process. Subsection 2 discusses the organization of conformity assessment at the international, regional and national levels and describes the ways in which conformity assessment requirements may impact on trade.

As mentioned in Section IIB, available databases on standards are not suitable for an economic analysis of the linkages between standards and trade. To a large extent, this also applies to the analysis of the linkages between standardization and conformity assessment infrastructure and trade. Data provide only a partial picture of the standards world, they are hardly comparable across countries, and they are not always reliable. Assessing standardization activity in a particular country and analysing its effect on trade is thus very difficult. Similarly, in the absence of estimates of the costs involved for governments to sustain conformity assessment infrastructure at the national level and to participate in international cooperation efforts, estimating the benefits from avoiding redundant conformity assessment procedures has been difficult.

1. STANDARDIZATION

When considering how standards are prepared and adopted in different regions and countries and how this affects trade, it is necessary to distinguish between types of standards in terms of how they have been developed. First, a distinction needs to be made between de facto and institutional standards. Institutional standards are those defined by committees and formally adopted, while de facto or informal standards are those that are not defined by committees, but rather are proprietary designs that win a position of market dominance. This Section will focus mainly on how institutional standards are developed.[48] A second useful distinction is between voluntary and mandatory standards, as discussed at some length in the previous Section. The way these two types of standards are developed can be different, and as much as possible both cases will be considered. Unfortunately, available data do not differentiate standards according to their *raison d'être*, their economic effects, or whether the standards relate to products, services or processes, mainly because the development processes associated with standards are generally not differentiated according to those criteria.

The way in which the formal standardization process is organized and the role assigned to various institutions differs significantly among regions and countries. First, standards are drawn up at the national, regional and international levels and the degree of "vertical" integration between those levels differs from one region/country to the other. Second, the degree of "horizontal" integration of the standardization bodies also differs among countries. In some countries, the standardizing process is very centralized at the national level, with one single body in charge of developing both voluntary and mandatory standards. In other countries, a large number of organizations produce voluntary standards, some of which become mandatory by being referred to in technical rules and regulations drafted by government agencies.

The participation of various stakeholders in the standardization process also varies among bodies and between countries. In some cases the only standardizing body is a government agency and all standards it produces are mandatory. In others, the role of the government is restricted to developing mandatory regulations, and to supporting the standardizing process, especially where voluntary standards will be referred to in technical regulations. Also, the participation of consumers, importers, exporters, producers, etc. can vary considerably from one body to another and among countries.

[48] For a survey of the literature on market processes creating de facto standards, see Swann (2000).

This Subsection looks more closely at how standards are prepared and adopted. It first examines the role of national, regional and international standardizing bodies. It then describes the standardization process and considers the various ways in which it can be organized, focusing in particular on the role of the public and private sectors, consumers and civil society. Building on this description of the institutional aspects of the standardization process, the issue of developing country participation in the international standardization process, an issue of particular importance from both a trade and development perspective, will be examined more closely.

(a) Where are standards set?

With the expansion of trade and the increasing integration of national economies, the standards development process organized by national, regional and international standards institutions has progressively evolved. The role of international bodies has gained prominence. Regional bodies have been created or developed and in many countries, national institutions have been reformed. The national standardization infrastructure in most industrialized countries is now integrated into the network of international standardization activities. However, a considerable number of low income and transition countries have not followed the trend. Their national institutions are not part of the international network.

While standardization activities at the international level, in particular the formal ones, are relatively easy to describe, the regional and national levels are considerably more complex. The World Standards Services Network provides comprehensive lists of international and regional standardizing bodies including links to their webpages. At the national level, useful sources of information are the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC), who publish directories of their national member bodies together with basic information on, for example, their resources and activities, the organizations to which standardization is delegated, the technical areas in which the bodies participate in standardization and the number of standards published.[49] Unfortunately, as explained below, this information only provides an incomplete picture of standardizing activities at the national level.

International level

Of the 49 international standardizing bodies listed by the World Standard Services Network[50] ISO, the IEC and ITU are the most important. As a network of national standards institutes of 148 countries, ISO is the world's largest developer of standards. Its scope extends to all fields except electrical and electronic engineering, the IEC's domain, and telecommunications, that of the ITU. The expansion of membership in both ISO and IEC over recent decades reflects the growing importance of international standards. While ISO and the IEC are non-governmental bodies, the ITU is part of the United Nations and its members are governments. IEC's full and associate Members, who currently number 65, are national committees – one for each country – which are required to be fully representative of all electrotechnical interests in the country concerned. ISO also liaises with 30 or so international standards-developing bodies outside the ISO/IEC system. Each of these bodies works in a specific area, usually with a UN mandate.

ISO and IEC standards are voluntary, but some are referred to in technical regulations and some become de facto mandatory. A certain number of their standards – mainly those concerned with health, safety or the environment – have been adopted in some countries as part of the regulatory framework, or are referred to in legislation for which they serve as the technical basis. Although voluntary, some ISO and IEC standards become a market requirement, as has happened in the case of ISO 9000 quality management systems, or of dimensions of freight containers, bank cards or electric batteries.

ISO and IEC together produce about 85 per cent of all international standards, and the other specialized bodies account for the rest. In 2004, ISO published 1247 international standards and standards-type documents, bringing the total number of international standards it published to 14,900 as of the end of 2004. The two main sectors of ISO standardization activities are materials technologies and engineering technologies, each of which accounts for about

[49] See Appendix Table 1 at the end of this Section.

[50] See Appendix Table 2 at the end of this Section.

a quarter of the total number of published standards. The IEC published some 397 standards and standards-type documents in 2004 and now counts more than 5,300 standards and standards-type documents in its catalogue, covering the fields of electricity, electronics and related technologies. Since the 1980s, ISO has started developing so called "generic management system standards". The ISO 9000 (quality management) and ISO 14000 (environmental management) standards are among ISO's most widely known and successful standards ever.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures encourages the use of international standards, guidelines and recommendations developed by WTO Member governments in other international organizations. These organizations are the joint FAO/WHO Codex Alimentarius Commission ("Codex") for food safety; the World Organization for Animal Health (previously the Office International des Epizooties "OIE") for animal health and zoonoses; and the FAO International Plant Protection Convention ("IPPC") for plant health. Most of the WTO's member countries are also members of these international bodies.

The Codex Alimentarius Commission was set up in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are to protect the health of consumers, to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations, and to ensure fair trade practices in food trade. Membership of the Commission is open to all Member Nations and Associate Members of FAO and WHO. In 2004, it had 171 member nations and one member organization. The Codex develops standards for food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. Codex develops both quality and safety standards.[51] On January 2005, the list of current official standards adopted by the Codex Alimentarius Commission included 214 standards, 52 recommended codes of practice and 45 principles and guidelines.[52]

At the time of the SPS negotiations in 1986, the IPPC was identified as the relevant international agreement for phytosanitary matters. However, at that time it had neither the mandate to develop international standards nor an international secretariat. The FAO, which had adopted the IPPC in 1951, thus established its Secretariat in 1992 and adopted the New Revised Text of the IPPC in 1997.[53] As of November 2004, the IPPC had 129 contracting parties. The goal of the IPPC is to secure action to prevent the spread and introduction of pests affecting plants and plant products, and to promote appropriate measures for their control.[54] The scope of the IPPC extends to items capable of harbouring or spreading pests, such as storage places, conveyances and containers. The Convention is legally binding. However, the standards that are developed and adopted are not. By the end of 2004, the IPPC had adopted 21 International Standards for Phytosanitary Measures (ISPMs) on issues ranging from pest risk analysis for regulated non-quarantine pests to guidelines for regulating wood packaging material in international trade. These standards can be reference standards, concept standards or related to a specific commodity, pest or measure.[55]

In 1924, twenty-eight states reached an "international agreement" to establish the OIE. The Agreement was ratified three years later.[56] The WOAH (previously OIE) produces four publications which contain comprehensive international standards and references for animals – the Terrestrial Animal Health Code, the Aquatic Animal Health Code, the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, and the Manual of Diagnostic Tests for Aquatic Animals. The aim of the Terrestrial and Aquatic Animal Health Codes is to assure

51 Codex has also developed guidelines for assessing the safety of Genetically Modified Organisms (GMO) food products.

52 Codex also established more than 2000 maximum pesticide residue limits which can be considered as standards. See http://www.codexalimentarius.net/web/standard_list.do?lang=en.

53 By the time of the SPS negotiations, the IPPC was implemented through the cooperation of member governments and regional plant protection organizations. When two-thirds of its contracting parties have ratified the 1997 amended IPPC text, it will come into force. Current information on the IPPC, including information relevant to International Standards for Phytosanitary Measures (ISPMs), can be found at http://www.ippc.int.

54 IPPC has also developed guidelines on how to assess the risks from living genetically modified organisms (LMOs) and from invasive species.

55 As of November 2004 the ICPM had adopted one reference standard which is updated annually (ISPM 5 Glossary of phytosanitary terms), one commodity specific standard (ISPM 15 Guidelines for regulating wood packaging in international trade) and 19 concept standards.

56 Current information on the OIE can be found at http://www.oie.int.

the sanitary safety of international trade in live animals, their genetic material and animal products. The codes describe health measures to be used by the veterinary authorities to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers. The purpose of the Terrestrial and Aquatic Manuals is to contribute to the international harmonization of methods for the diagnosis, surveillance and control of the diseases listed in the Codes. Standards are described for laboratory diagnostic tests and the production and control of biological products (principally vaccines) for veterinary use across the world. The standards published represent a consensus among the veterinary authorities of WOAH Member Countries. WOAH has recently begun work on standards for animal welfare. The WOAH's financial resources are derived principally from regular annual, as well as voluntary, contributions from member countries.

Over the past 20 years, the role of NGOs in the development of international standards has gained importance. Growing public awareness of environmental and social issues has given rise to a number of standard setting, certification, and labelling initiatives, some led by NGOs and others led by the business sector. As discussed below, NGO interest in ISO has increased considerably since ISO started developing generic management system standards in the 1980s. At the same time, an increasing number of NGOs have started developing standards themselves. The ISEAL Alliance, for instance, is an association of leading international standard-setting, certification and accreditation organizations that focus on social and environmental issues.[57] ISEAL has eight full members and two associate members. The full members are: Fairtrade Labelling Organizations (FLO), the Forest Stewardship Council, the International Federation of Organic Agriculture Movements, the International Organic Accreditation Service, the Marine Aquarium Council, the Marine Stewardship Council, the Rainforest Alliance, and Social Accountability International. The associate members are: the Global Ecolabelling Network, and Chemonics International.

Box 8: NGOs as standardizing bodies: Fairtrade Labelling Organizations

The past decade has seen the proliferation of environmental and social labels along with increasing public awareness about issues in both domains. In this area NGOs have proven to be effective in promoting, leading and coordinating standardization and labelling initiatives and they have been competing with traditional international organizations.

Among the many examples of NGO-driven standardization efforts, fair trade is one of the most prominent. According to FINE[1], fair trade can be defined as "a trading partnership, based on dialogue, transparency and respect that seeks greater equity in international trade. It contributes to sustainable development by offering better trading conditions to, and securing the rights of, marginalized producers and workers – especially in the South." Although the concept was introduced 40 years ago, the diffusion of fair trade products remained marginal until recently. Officially founded in 1999 in an effort to unify the different labelling initiatives, and to increase the reach and impact of fair trade, Fairtrade Labelling Organizations International (FLO hereafter) is widely recognized as the leading fair trade standard setting and certification organization. FLO is made up of 19 National Members (e.g. Max Havelaar in France and Switzerland, TransFair in Canada, Germany and the US, FairTrade in Japan), representing 20 nations. Their role is to promote and market FLO-labelled products through various channels in their respective countries.

FLO standards

Standards developed by FLO apply to a range of agricultural products (e.g. coffee, fresh and dried fruits, flowers, rice) and, for the time being, to one manufactured product (sport balls). These products are typically, but not exclusively, produced in developing countries. Standards set both minimum (to be met immediately) and progress (to be met in the future) requirements mainly for production processes, which include labour conditions (largely based on ILO standards) and environmental and social impact, as well as for product characteristics and performance.

57 See http://www.isealalliance.org/about/index.htm

When a stakeholder sees the need for a new standard or a revision of an existing one, the FLO Standards & Policy Committee initiates a research phase during which all relevant stakeholders are consulted. Then, based on its observations, the Committee drafts a proposal for discussion. Next, a final draft is published in line with the ISEAL Code of Practice on Standards Setting.[2] Finally, the draft goes to the FLO Board of Directors for ratification.

In addition, to ensure the dedicated portion of the price paid by consumers for a Fairtrade Product effectively reaches the producer, FLO exercises control over the whole supply chain by certifying trading companies willing to respect the Fairtrade Trading Standards. These standards regulate the relation between traders and producers (payment of a minimum price covering costs of sustainable production and living, payment in advance if necessary, signing of long-term contracts). One of the key actors in this 'Fairtrade chain' is the licensee, defined as a company, usually a retailer, that has entered into a License Contract with a FLO National Member for the use of a Fairtrade Label on the product for final sale to consumers.

Certification

While some NGOs acting as standardizing bodies (e.g. Forest Stewardship Council, Marine Stewardship Council, International Federation of Organic Agriculture Movements, Fair Labor Association) outsource certification to accredited bodies, FLO created its own certification body, the FLO Certification Unit, which has since become a limited company, FLO-Cert Ltd. When a producer is interested in becoming Fairtrade certified he addresses a request to FLO. FLO then runs a preliminary check to determine whether the producer meets the minimum requirements set by the standards. If the producer meets the requirements, FLO performs an inspection visit on which the Independent Certification Committee will base its decision to attribute the Fairtrade label. To formalize the commitment, a contract is signed between the producer and FLO.

FLO sets initial certification fees to be paid by producers, according to their size (in terms of employees) and their nature (plantations or cooperatives). The fee ranges from €2,000 to €5,200. The fee for certification renewal depends on the volume sold in the previous year and the kind of product. As of May 2004, there were 389 certified producers, 350 registered traders and 550 licensees.

Metric tons of FLO-labelled products sold

	2000	2001	2002	2003	2002/03 growth	2000/03 growth
Bananas and fresh fruit	22819	29072	36641	52999	45%	132%
Cocoa products	1153	1453	1656	3473	110%	201%
Coffee	12818	14432	15779	19895	26%	55%
Honey	961	1071	1038	1164	12%	21%
Juices	711	966	1387	1890	36%	166%
Sugar	357	468	650	1164	79%	226%
Tea	931	1085	1266	1989	57%	114%

Source: FLO, September 2004.

For more details, see the following links:
– Fairtrade Labelling Organisations International: www.fairtrade.net
– ISEAL Alliance: www.isealalliance.org
– European Fair Trade Association (EFTA): www.eftafairtrade.org

[1] FINE is a network formed by four organizations, namely FLO, IFAT, NEWS! and EFTA, in order to share information and to coordinate lobbying and awareness-raising efforts in the area of fair trade.

[2] The ISEAL Alliance is an association of leading international standard-setting, certification and accreditation organizations that focus on social and environmental issues.

Regional level

At the regional level, emphasis in trade negotiations is progressively shifting from conventional barriers towards standards. In most regions, initiatives aimed at reducing the trade-restrictive impact of technical barriers have been implemented or announced. Integration in the area of standards and technical regulations is probably most advanced in Europe. Before the creation of the European Union, each country imposed its own technical requirements. Differences between national laws, standards, and conformity assessment procedures made trade difficult, contentious, and expensive. As discussed in the previous Section, a new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonization and standardization (see Box 9). This New Approach was designed to harmonize the health, safety, and environmental requirements of Member States into one European-wide legislative package. Secondly, with regard to conformity assessments, a new integrated scheme, the so-called Global Approach, was adopted. Thirdly, a new, integrated, European system of standardization was established to eliminate the technical barriers resulting from the differences between the national standards of the 15 Members.

Box 9: The new approach to technical harmonization and standardization in Europe

In the European Union, new barriers to trade resulting from the adoption of diverging national technical standards and regulations can be prevented through a series of provisions laid down by Directive 98/34/EC. Those provisions involve the obligation to notify draft technical regulations to the Commission and to other Member States, and standstill periods of various lengths to allow for objections. National technical regulations are subject to the provisions of Articles 28 and 30 of the Treaty establishing the European Community. The regulations prohibit quantitative restrictions or measures having equivalent effect. Case law of the European Court of Justice, especially the "Cassis de Dijon" case, provides the key elements for mutual recognition. Products legally manufactured or marketed in one country should in principle move freely throughout the Community. Barriers to trade which result from differences between national legislation may only be accepted if national measures are necessary to satisfy mandatory requirements such as health, safety, consumer protection and environmental protection. Restrictions on the free movement of products which may be acceptable under Article 28 and 30, can only be eliminated through technical harmonization on Community level. However, regulating and harmonizing laws for every product with specific, highly technical requirements for each proved to be an impossible task.

The New Approach to technical harmonization and standardization, introduced in 1985, established four main principles. First, legislative harmonization is limited to essential health and safety requirements that products placed on the EU market must meet if they are to benefit from free movement within the EU. Second, the technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonized standards. Third, application of harmonized or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements. Fourth, products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements.

The New Approach governs the families of products listed below:

- Appliances burning gaseous fuels (90/396/EEC)*
- CE marking directive (council directive amending other directives) (93/68/EEC)
- Construction products (89/106/EEC)
- Electromagnetic compatibility (89/336/EEC)
- Energy efficiency requirements for household electric refrigerators, freezers, and combinations thereof (96/57/EC)
- Equipment and protective systems in potentially explosive atmospheres (94/9/EEC)
- Explosives for civil uses (93/15/EEC)

- Interoperability of trans-european high-speed rail system (96/48/EC)
- Lifts (elevators) (95/16/EC)
- Low voltage equipment (73/23/EEC)
- Machinery, safety of (98/37/EC)
- Marine equipment (96/98/EC)
- Medical devices: active implantable (90/385/EEC)
- Medical devices: general (93/42/EEC)
- Medical devices: in vitro diagnostic (98/79/EC)
- Non-automatic weighing instruments (90/384/EEC)
- Packaging and packaging waste (94/62/EC)
- Personal protective equipment (89/686/EEC)
- Precious metals (not formally proposed) (Com(93)322)
- Pressure equipment (97/23/EC)
- Pressure vessels, simple (87/404/EEC)
- Radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (1999/5/EC)
- Recreational craft (94/25/EC)
- Toys, safety of (88/378/EEC)

For products that are not governed by New Approach Directives, there are essentially two regulatory levels. Technical requirements differ for each of them. There are the "old approach" regulations, which have technical specifications integrated into the annexes. Some of these products are regulated on a product-by-product basis. Other products are unregulated at the EU level, but may be regulated at the national level and are governed by Member State laws.

All manufacturers, domestic or foreign, are obliged to meet all the essential requirements pertaining to their product. The law does not distinguish between European manufacturers and manufacturers of other countries.

The point of the New Approach Directives was to eliminate differences among national laws that caused barriers to trade. But differences in national standards and testing and certification procedures were the root causes of barriers to trade, and it followed that a new, integrated scheme for technical harmonization had to be implemented as well. The new scheme was embodied in two Decisions: the Module Decision and the regulation on CE Marking. The policy was called the Global Approach. Finally, conformity assessment can be carried out with or without the use of standards. This last principle is important to manufacturers of new or innovative products for which standards do not yet exist, and ensures that standards annexed to New Approach Directives (which are voluntary) do not become *de jure* obligatory.

For more details, see the Guide to the Implementation of Directives Based on New Approach and Global Approach, (http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm)

or

Delaney and van de Zande (2000) A guide to EU standards and conformity assessments, NIST Special publication 951, (http://ts.nist.gov/ts/htdocs/210/gsig/eu-guides/sp951/sp951.htm)

* Directive number.

The responsibility for European standardization lies primarily with the European Committee for Standardization (CEN), founded in 1961 and the European Committee for Electrotechnical Standardization (CENELEC), founded in 1959. The European Telecommunications Standardization Institute (ETSI) was established in 1988 for standardization in telecommunications. CEN and CENELEC consist of the 28 standardization organizations

of the European Union and EFTA. ETSI, on the other hand, is open to all organizations which are interested in the standardization of telecommunications. The three organizations develop European standards that must be transposed into national standards. Note that this does not make European standards mandatory. European Standards only become mandatory if they are referred to in legislative texts. Although most are initiated by industry, a significant number of standards have been developed to support European legislation. Reference to standards in legislative texts is seen as a more effective way of ensuring that products meet the essential health and safety requirements of legislation, rather than the writing of detailed laws (Box 9).

By November 2004, the total number of European Standards and approved documents published by CEN amounted to 10,331, with another 6,772 documents in preparation (end December 2003). The total number of active European standards published by CENELEC was 4,377 (end of 2002), while the corresponding figure for ETSI was 1,798 (end of 2003). The three institutions also produced a small number of standards that are not European Standards.

In other parts of the world, initiatives aimed at developing regional integration of standardization activities have achieved mixed results. In Africa, for instance, the African Regional Organization for Standardization (ARSO) was established in 1977. ARSO, an inter-governmental organization, currently has 24 member states. The objectives of ARSO are to promote standardization activities in Africa, to elaborate and harmonize regional standards, to promote social, industrial and economic development and provide consumer protection and human safety by advocating and establishing activities concerning standardization in Africa. ARSO also seeks to promote common views among its members and to coordinate participation at the international level in the field of standardization. In 2002, ARSO had published around 400 African regional standards, but progress in recent years has been limited.[58] Work on regional harmonization of standards has, however, been successfully initiated in the Southern African Development Community (SADC). In addition, the East African Community has notified a number of regional standards to other WTO Members and is harmonizing standards within the community.

Regional and international standardization activities tend to be closely connected in most regions. ISO and IEC have both recognized a number of regional standards organizations. Recognition is based on a commitment by the regional bodies to adopt ISO/IEC international standards – whenever possible without change – as the national standards of their members and to initiate the development of divergent standards only if no appropriate international standards are available for direct adoption. ISO's ten partner organizations represent Africa (1), the Americas (1), the Arab States (1), Asia and the Pacific (2), the Commonwealth of Independent States (1), and Europe (4). Several hundred other regional organizations liaise with ISO technical committees without being formally recognized by ISO. They are mainly regional associations of producers such as the American Association of Cereal Chemists (AACC), the European Association of Aerospace Industries (AECMA-STAN), and the European Association of Manufacturers of Quality Metal Expansion Joints, Metal Bellow and Metal Hoses (AEO).

National level

The role of national standardization institutions and the number of standards they produce differs significantly among regions and countries. First of all, both the demand for standards and the capacity to implement standardization infrastructure and activities depend on various factors, many of which are correlated with the country's level of development. The demand for standardization services increases with the level of prevailing scientific, technical and business capacity, the level of industrialization, the degree of economic diversity, the importance of export markets, and the evolution of domestic consumer needs.[59] It also depends on country specific factors such as country size, the form of industrialization, the degree of concentration of industrial sectors, and prevailing administrative and political structures and cultural norms.

On the supply side, the availability of resources is clearly a principal determinant. However, standardization requirements can be addressed in different ways. A variety of alternatives exist for establishing or enhancing national

[58] Opening Remark on the 12th ARSO General Assembly by H.E. Mr. Girma Biru, Minister of Trade and Industry, Ethiopia, Addis Abbaba, 2004.

[59] See Henson (2004).

standardization capacity in the form of a national standards body. Existing organizations, such as government departments, professional bodies, and industry and trade organizations can be used. Industrial and trade practices already established and applied in the country can be built upon, whether these are formally constituted through legislation or have developed less formally. Standards of neighbouring countries, trading partners or international standards can also be used. Finally, regional standardization infrastructure can be developed.

At a given level of development, national standardization systems may differ significantly with regard to their degree of centralization, formalization, and participation by the government. Chart 3 sets out four alternative approaches to standards development at the national level, all with a different mixture of government versus private sector involvement. The North American model for standards development is very decentralized and market-oriented. Over 600 organizations in the United States develop and implement national standards. A large number of private sector standards-developing institutions co-exist with the numerous regulatory agencies of the US Government. In the Canadian system, both the private sector and the central government are actively involved. In Western Europe, standard development activities have traditionally been much more centralized. As explained above, the European Commission has the responsibility for harmonizing standards of EU Members when possible, or with setting out "essential requirements" that products must meet.

The diversity of standardizing systems among developing countries reflects the diversity of approaches in Chart 3, combined with the diversity related to different levels of development. In many countries, the traditional approach to standardization adopted in industrialized countries in the past still prevails. In others, a new approach better suited to address greater levels of industrialization and internationalization progressively replaces the old one. The differences between the traditional and the new approaches are summarized in Table 4. The traditional approach focuses primarily on domestic concerns with little or no consideration of standards in export markets. Standards institutions are generally found in the public sector with little or no participation of the private sector. Standards are mostly mandatory. Institutions are rather static, inflexible and bureaucratic. The new approach focuses more on the specific concerns of industry and commerce. Standards must comply or be compatible with international norms and the testing and certification elements need to be recognized internationally. Standards institutions must be flexible, dynamic and efficient, so as to respond in a timely fashion to changes in demand for standards.

Table 4
Traditional and new approaches to standardization

Traditional approach	New approach
Key objectives:	
• Weights and measures	Domestic and external focus
• Health and safety	Extended infrastructure
Static structure	Flexible and dynamic structure
Domestic focus	Public-private sector activity
Public sector activity	International recognition
Regulatory focus	Voluntary standards

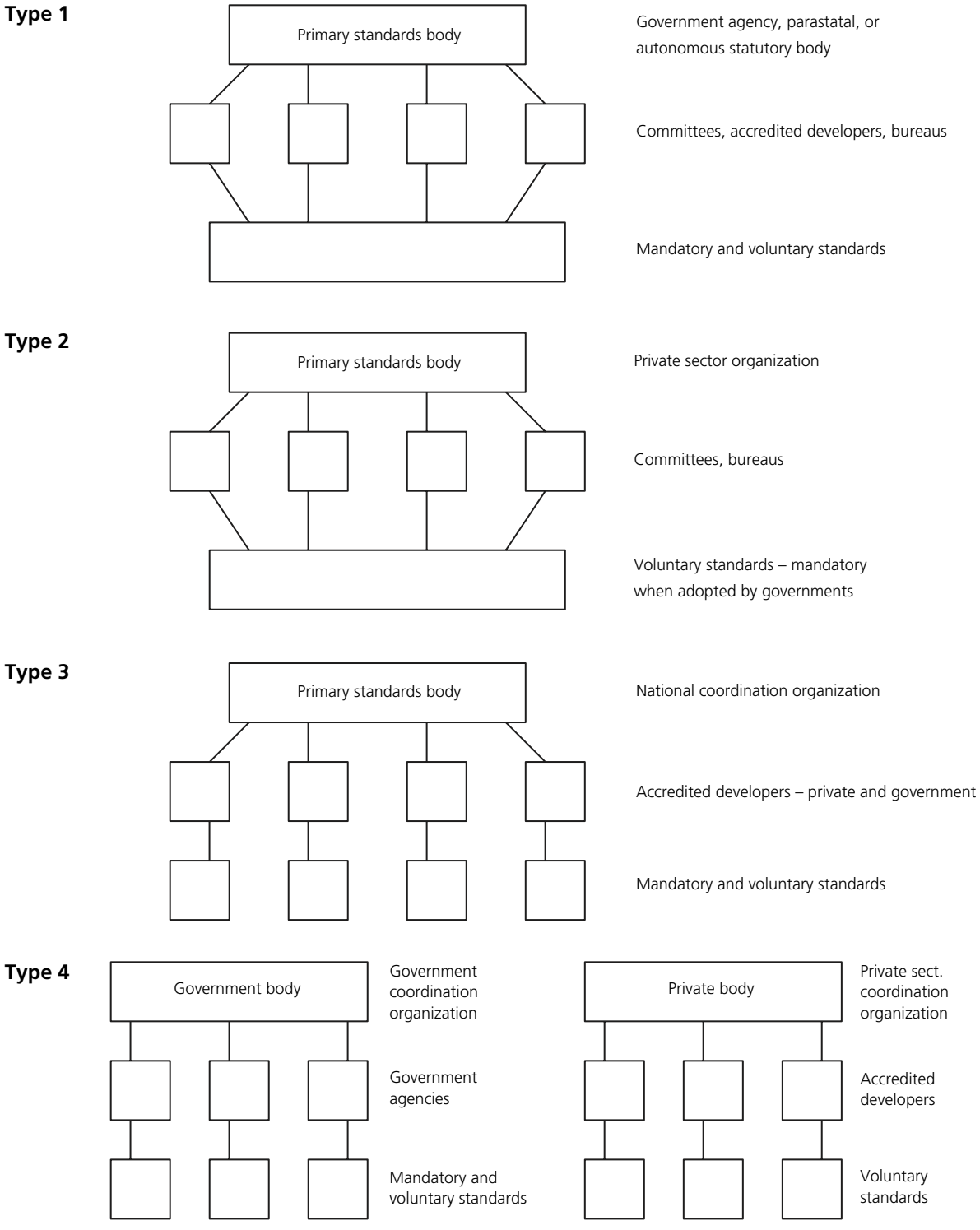
Source: Henson (2004).

Comparable cross-country information on national standards systems is limited. The International Organization for Standardization (ISO) publishes a Directory of ISO Member Bodies. The last issue of the Directory, which was published in 2003, provides information on ISO's 97 Member Bodies, 35 Correspondent Members, and 15 Subscriber Members. Chart 4 shows the number of each type of Member by region. A Member of ISO is the national standards body "most representative of standardization in its country". It follows that only one such body for each country is accepted for ISO membership. A Correspondent Member is usually an organization from a country that does not yet have a fully developed national standards activity. Correspondent Members do not take an active part in ISO's technical work and have no voting rights, but they are entitled to attend meetings as observers and to be kept fully informed about the work of interest to them. Finally, Subscriber Members are from countries with very small economies. They pay reduced membership fees that nevertheless enable them to keep up to date on international standardization activities.

Information in the ISO Directory provides an incomplete description of most national standards systems.[60] Where the system is completely centralized with the ISO Member body in charge of developing all standards,

[60] Information in the Directory is provided by ISO members who fill out a standard questionnaire. The questionnaire is designed to structure the information so as to enhance comparability. However, ISO warns readers that caution should be exercised in making comparisons as some questions might have led to different interpretations.

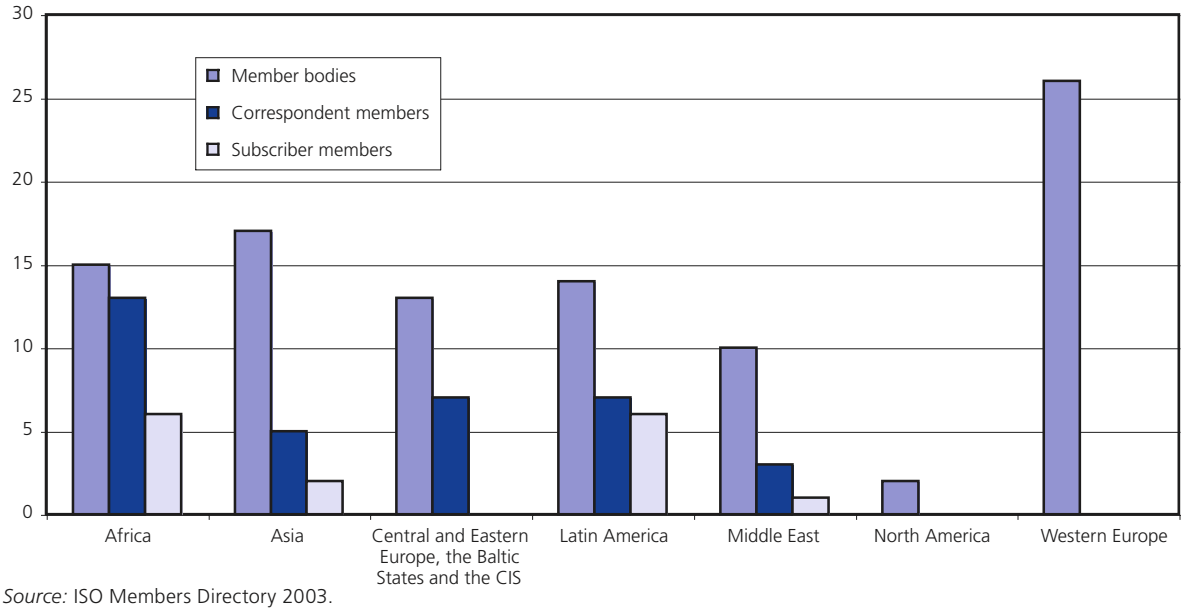
Chart 3
Alternative approaches to standards development



Source: R.B. Toth Associates, in Stephenson (1997).

whether mandatory and voluntary, the description can be fairly comprehensive. However, where the standardization process is decentralized and not entirely coordinated by the ISO Member body, and/or where the ISO Member body is not responsible for issuing technical regulations, the picture is incomplete. While a considerable amount of theoretical economic analysis has focused on de facto standards, systematic empirical information on such standards is typically limited. Standard setting by NGOs is another phenomenon that is not well documented.

Chart 4
Number of ISO Members by categories and by region



Source: ISO Members Directory 2003.

Table 5 provides basic information on standardization activities by ISO Member bodies by region. The average number of staff employed by ISO Members varies significantly among countries, even in the same region. AFNOR, the French Member body, employs 630 persons while the British Standards Institution employs 5175. The low figures for staff and total number of standards published for North America reflect the limited centralization of the systems in this region. In reality, more than 600 organizations develop voluntary standards in the United States.[61] About 150 of them are consortia which develop de facto standards. Most are private sector organizations – professional and technical organizations, trade associations, research and testing bodies, building code organizations, and others. At the national level, the United States maintains about 100,000 standards in an active status. This figure includes Federal Government standards developed to meet procurement and regulatory needs.[62] Trade associations represent the largest category of non-government standard developers. Many standards-developing organizations follow American National Standards Institute criteria in order to have the consensus standards they develop approved as American National Standards. There were approximately 14,650 approved American National Standards in 1999.

Table 5
Staff, related bodies, and standards published by ISO Members, averages across ISO member bodies by region

	Average number of staff directly employed by ISO Member	Average number of organizations to which standards development work is delegated	Average total number of standards published by 31/12/2002
Africa	186	41	1281
	(28)	(7)	(27)
Asia	319	296	5052
	(21)	(10)	(23)
Central and Eastern Europe, Baltic States, CIS	220	102	12598
	(19)	(15)	(19)
Latin America	124	10	2085
	(23)	(7)	(25)
Middle East	276	4	1916
	(12)	(7)	(12)
North America	83	99	2143
	(2)	(2)	(1)
Western Europe	398	29	15407
	(25)	(15)	(26)

Note: Number of observations in parenthesis.
Source: ISO Members Directory 2003.

61 See De Vaux (2001).

62 As of 1991, the total of US government standards (federal procurement and regulatory) stood at around 52,000, while the number of private sector voluntary consensus standards numbered around 42,000. See Toth (1991).

(b) How are standards set?

As already mentioned, standards are developed in different ways. This Subsection focuses mainly on the development process of voluntary, consensus-based standards and in particular on the formal/institutional procedure used by ISO and many of its Member bodies.[63] Mandatory standards (technical regulations as well as sanitary and phytosanitary measures) which are legal instruments that are elaborated by governments, are discussed in less detail. De facto industry standards are created by market processes that have been analysed in detail by economists.[64]

Voluntary, consensus based standards

The two main documents which regulate standardization procedures used by ISO, the IEC and most of their Members, are ISO/IEC Guide 59, *Code of good practice for Standardization* and the WTO's *Code of Good Practice for the Preparation, Adoption and Application of Standards* in Annex 3 of the Agreement on Technical Barriers to Trade (TBT). In addition, the ISO/IEC Directives, which cover the procedures for the technical work, and the rules for the structure and drafting of International Standards, are important reference documents. ISO and IEC have published independent supplements to the main Directives, which include procedures that are not common to the two organizations. All forms related to the process of standards development are given in the respective Supplements to the ISO/IEC Directives. As explained in Section IID below, the WTO TBT Agreement requires WTO Members to ensure that their central government standardizing bodies accept and comply with the Code in Annex 3, and to take reasonable measures to ensure that local government, non-governmental and regional standardizing bodies do the same. As of February 2003, 139 standardizing bodies from 101 Members have accepted the Code of Good Practice – among them, 71 central governmental standardizing bodies, 59 non-governmental standardizing bodies, two statutory bodies, two parastatal bodies, three non-governmental regional bodies, one central governmental/non-governmental body, and one autonomous body.[65] The Code aims to ensure that technical regulations and standards do not create unnecessary obstacles to trade. Note that other organizations have elaborated codes of good practice for the development of standards. The ISEAL Alliance, for instance, has developed a Code of Good Practice for Setting Environmental and Social Standards.[66]

The development of formal voluntary consensus standards is a process that consists of several distinct but closely related activities. The first stage is the identification of the various needs for standards and the prioritization of those needs given the resource constraint faced by the standardization infrastructure. The second stage is the development of the standard, usually through the establishment of a technical committee involving all parties interested in the area. The third stage corresponds to the adoption of the standard either by consensus or by vote. The fourth and last stage is the publication and promotion of the standard. Ideally, the process should be such that it can satisfy the needs of users as rapidly and efficiently as possible.

Prioritizing the needs, which can be identified in a variety of ways, is essential to ensure the most efficient use of resources. The process of needs identification can be more or less formal. The national standards body usually consults and communicates with users, government, etc. It may organize a formal consultation process and/or may accept unsolicited proposals for new standards. An important issue at this stage as well as at later stages is participation, which is discussed in more detail in the next Subsection. Producers who have clear priorities and are usually better organized than consumers typically play the leading role. In some industrial countries, governments actively promote the participation of consumers by funding consumer organizations. Once the needs are identified, they must be prioritized. Economic and social priorities will differ among countries. Poorer countries, for instance, may prioritize standards that facilitate access to export markets over standards that address minor food safety risks.

63 ITC and Commonwealth Secretariat (2004) describes the procedures for the establishment of standards of ISO, IEC, ITU, the International Organization of Legal Metrology, the World Health Organization, the Codex Alimentarius Commission, the World Organization for Animal Health, and the International Plant Protection Convention.

64 The greater part of the mainstream economics literature on standards has been theoretical. See Swann (2000).

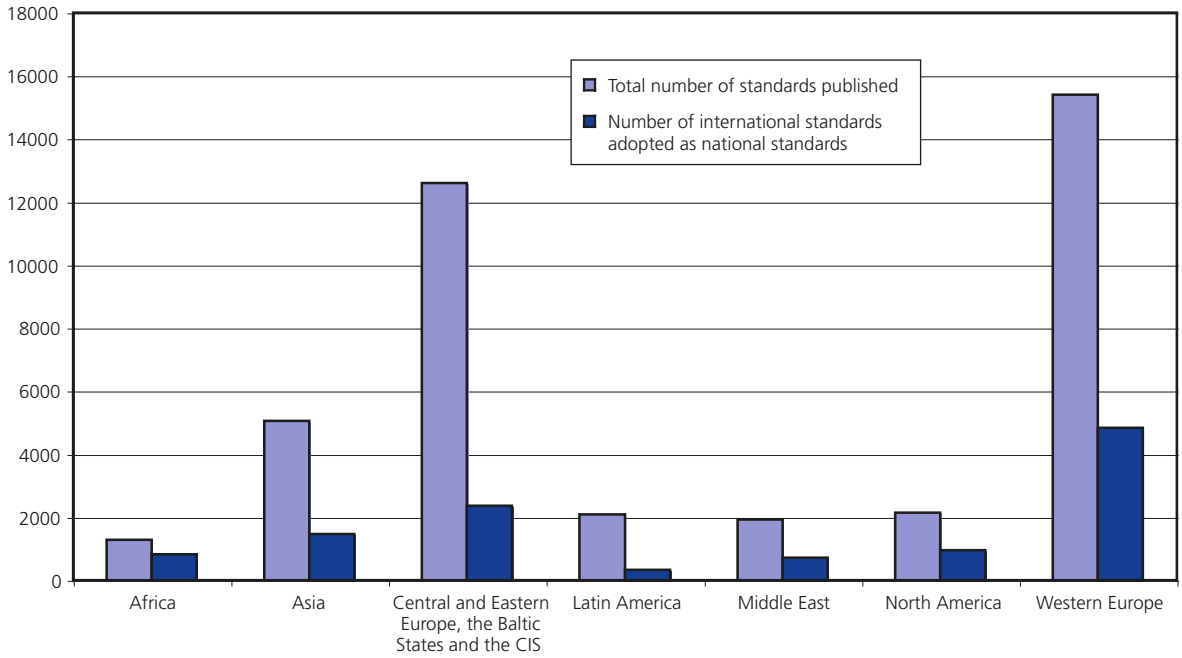
65 See WTO document G/TBT/CS/2/Rev.9.

66 See http://www.isealalliance.org/documents/pdf/P005_PD3.pdf and Dankers (2003) for a discussion of social and environmental standards.

In setting priorities, standardizing bodies need to take into account the possibility of adopting or adapting regional or international standards, or of proposing the development of new standards at the regional or international levels. As already mentioned, some countries are well integrated into the international standardizing system and a principle of "subsidiarity" applies. In Europe, for instance, adoption of European standards is mandatory for national member bodies and European standards organizations transpose the international standards into European standards. Indeed, more than 30 per cent of the European Standards adopted by CEN and more than 70 per cent of those adopted by CENELEC are identical to ISO and IEC International Standards, respectively, and many more are closely related. Furthermore, European standardization projects have absolute priority over national ones, as according to a so-called obligatory standstill agreement, no national standardization proceedings may be started in the areas in which European standards are to be established.[67] In ASEAN Member States, there is an agreement that national standards in selected priority areas should be aligned with international standards. In Malaysia, for instance, national standards are harmonized with international standards wherever possible. Thirty-eight percent of Malaysian standards are aligned with international standards and this proportion is rapidly growing as more standards are revised and new standards are developed.

Smaller and poorer countries also seek to keep within the guidelines of the WTO and increasingly adopt regional or international standards.[68] Contrary to expectations, countries with scarce resources and limited capacity do not necessarily have the largest share of adopted international standards. In fact, resource constraints seem to restrict poor countries' integration into the international standardization system as much if not more than they restrict their own standardization activities. As discussed below, integration into the international system involves a certain level of participation in the international standardization process, as well as the setting up of a standardization infrastructure. Developing one's own standards in isolation can be less resource intensive. Another relatively cheap solution may be to adopt the standards of your main trading partner. In Namibia, for instance, the manufacturing sector relies on South African standards. Manufacturers do not know whether these South African standards are identical to international standards but assume that they are equivalent.[69] Chart 5 below shows the average number (across countries) of international standards adopted as national standards by region.

Chart 5
Total number of standards published and number of international standards adopted by national standard bodies (31/12/2002), averages by region



Source: ISO Members Directory 2003.

67 See Blind (2004).

68 See the case studies in ITC and Commonwealth Secretariat (2003 and 2004).

69 See ITC and Commonwealth Secretariat (2004).

At the international level, industries or business sectors that feel the need for a standard communicate their requirements to the appropriate ISO or IEC national member body, which then proposes a new work item. If the proposal is accepted by a majority of the participating members in the ISO or IEC technical committee concerned, the work item is assigned to that committee.[70] At the European level, the application for a new standardization project can only be submitted by the Member organizations or committees of CEN/CENELEC, by the European Commission, the EFTA Secretariat or European specialist organizations. In Germany, applications for standardization are submitted by enterprises or groups of enterprises and accepted or rejected by the relevant technical committee, but only after having been examined by the standardization institute. In South Africa, requests come from industry or government, although persons or organizations submitting the relevant motivation may also propose standards.[71] They are approved (or rejected) by the Standards Approval Committee, based on an assessment of market relevance, cost of development and a recommendation from the appropriate national Technical Committee. The final decision as to which route to follow when a new standards project comes under consideration is taken by the responsible committee. However, Standards South Africa is committed, wherever possible, to encouraging committees to adopt international or regional standards, since this will ultimately result in wider standardization, with all its benefits, on a global scale.

The most common method for developing standards is through the establishment of technical committees involving all parties interested in the area. These technical committees are responsible for preparing draft standards that are acceptable to all parties and can be submitted for approval. Because the drafting and consensus-building process can be lengthy, the temptation to limit consultations is considerable. However, the success of the standard depends largely on the participation of all interested parties. ISO standards, for instance, are developed by technical committees comprising experts from the business sectors which have asked for the standards, and which subsequently put them to use. Those experts, which participate as national delegations, meet to discuss, debate and argue until they reach consensus on the technical content.[72] Once consensus is attained, the text is finalized for submission as a draft International Standard. Altogether, there are 190 active Technical Committees in ISO today, the technical work of ISO, which is highly decentralized, is carried out in a hierarchy of some 2,940 technical committees, subcommittees and working groups.[73] In the IEC, each member National Committee handles the participation of delegates from its country. Some 179 technical committees and subcommittees, and about 700 project teams / maintenance teams, carry out the standards work. The great majority of the working group experts come from industry, while others from commerce, government, test and research laboratories, academia and consumer groups also contribute.

The final decision regarding adoption of the standard can be taken either by vote or by consensus. In the case both of ISO and IEC, the draft international standard is submitted twice to all the individual organization's member bodies for voting and comment – first at the enquiry stage, then at the final approval stage. The text is approved as an international standard if at both stages, a two-thirds majority of the participating members of the technical committee are in favour and not more than one-quarter of the total number of votes cast are negative. Similarly, a draft European standard is first released for public comment. During the public commenting stage, anyone who is interested may comment on the draft. These views are collated by the National Standards Bodies and sent to the CEN Technical Committee for consideration. European Standards are then adopted by the National Standards Bodies which make up CEN through a system of weighted votes. The final stage of the process is the publication, distribution and promotion of the standard. In the European case, the last stage also entails the transposition of the European Standard at the national level.

The philosophy of standardization by committee and consensus is the same in the EU as it is in the United States. Technical experts and others participate voluntarily, and without compensation. The makeup of committees may be organized differently and roles may vary, but they generally follow a pattern that includes input from producers, users, government, and academia. In both jurisdictions, committees are fairly autonomous, with processes for the creation of subcommittees, drafting standards, disseminating draft

70 See the detailed procedures at http://www.iso.org/sdis/directives.

71 See http://www.stansa.co.za/pdf/Standards_2003.pdf

72 In order to participate in the work of Technical Committees, a national member body informs ISO Central Secretariat whether it intends to act as a Participating or Observing member. See the discussion on participation below.

73 As of January 2005, see ISO website: "List of technical committees".

documents for comment, voting, and appeals. Decisions are reached by consensus. Standards organizations provide management, administrative, and logistical support for standards activities. They also provide for the editing, printing, publishing, sale, and distribution of standards documents.[74]

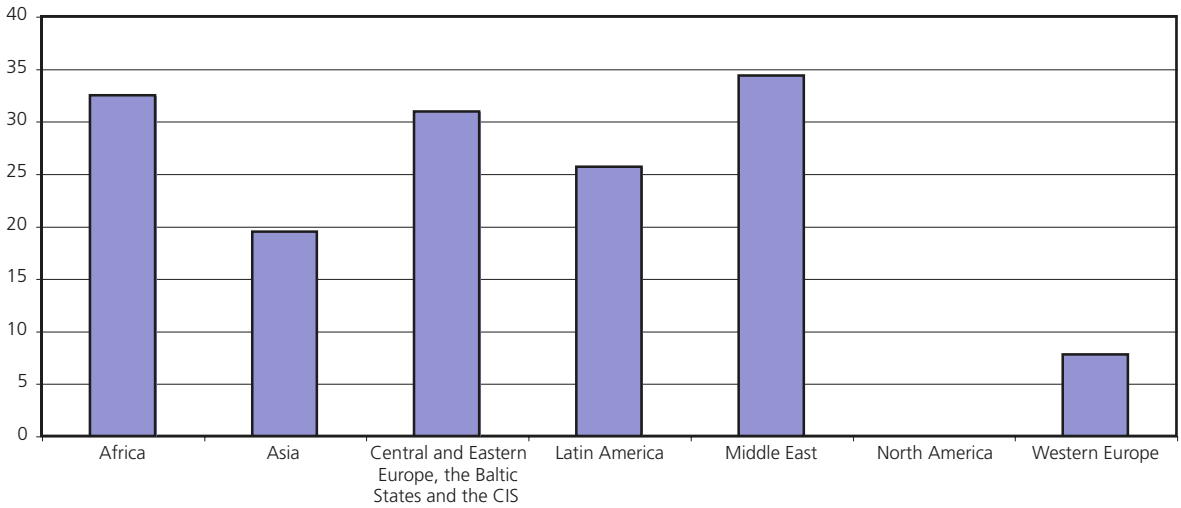
The whole process can be time consuming, although the IEC has recently succeeded in reducing delivery time for half of its standards to less than three years and, in Europe, CEN has embarked on a programme which aims at delivering most European Standards in that time. To respond to the needs of standards users working in fast-changing sectors, and to face the challenge of informal standards, ISO and IEC have developed streamlined procedures which can be used at the discretion of those technical committees for which speed of standards development is a paramount consideration, and to rationalize the set of deliverables. In this streamlining effort, both organizations have introduced new deliverables that inevitably reduce levels of transparency and consensus, but which seem to respond to market requirements in some sectors.

Mandatory standards

The WTO Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary Measures discipline the preparation of mandatory standards, technical regulations and sanitary and phytosanitary (SPS) measures. Section IID below discusses the relevant provisions in those two Agreements in some detail. At this stage, it is useful to mention that both WTO Agreements encourage governments to base technical regulations on international standards and to play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of the relevant international standards. In the case of Switzerland, for instance, the government may decide to support financially or otherwise the development of such standards or to mandate national standardizing bodies to defend their national interests in international standardizing bodies.[75]

While in many countries, mandatory standards and technical regulations are typically developed by governmental agencies distinct from the standardizing bodies, in other countries standardizing bodies develop both voluntary and mandatory or even only mandatory standards. Chart 6 below shows the percentage share of mandatory standards in the total number of standards developed by standardizing bodies, by region. In a small number of countries, mainly in Africa, the CIS and the Middle-East, the share of national standards with a mandatory status exceeded 50 per cent of the total number of standards published at the end of 2002.[76]

Chart 6
Share of mandatory standards in total number of standards developed by national standard bodies, average by region



Source: ISO Members Directory 2003.

74 See Delaney and van de Zande (2000).

75 See Art 11 of the Swiss Federal Law on Technical Barriers to Trade (Loi fédérale sur les entraves techniques au commerce) at (http://www.admin.ch/ch/f/rs/946_51/a11.html).

76 See ISO Members Directory 2003.

It is interesting to note that voluntary standards sometimes become de facto mandatory. In the United States, for example, wholesalers or retailers sometimes refuse to sell non-standard products because they do not wish to bear the responsibility in cases where such products create problems.

(c) Who sets the standards?

The issue of participation in the standard-setting process is crucial. In this Subsection the participation of producers, consumers and other stakeholders will be discussed. Participation by developing countries in the international standard setting process is addressed in Subsection (d), while transparency and national treatment – both aspects of crucial importance from a trade perspective – are discussed in Section IID below. While participation at the regional and national levels are considered, the focus is on standard setting at the international level, and in particular in ISO. As explained below, ISO's expansion beyond technical standards for specific (mostly manufactured) products or technologies into the development of "process" standards has substantially extended the range of stakeholders interested in participation.

The discussion in Section IIB identified two main reasons for government involvement in standardization. First, governments are responsible for issuing technical regulations and making certain standards mandatory. Second, depending on the problem standards are supposed to solve, public intervention is warranted. This is because governments are expected to take into account the interests of all economic actors when setting standards, whereas private companies will be driven by the aim of maximizing profits. Uneven representation in the standardization process can lead to short-sighted standards and there is doubt that a producer-led standardization process can give full account to customer interests, a result that has been pointed out frequently in the economic literature (Casella, 2001). This is particularly important from a trade perspective, as producers might have an incentive to use standards to create artificial competitive advantage.

Where government intervention is warranted to defend consumer interests, it can take different forms. Most of the time, governments do not possess the information needed to develop standards and thus rely on information provided by producer and consumer representatives. Their intervention may thus take the form of support to consumer participation in private or non-governmental standardization bodies. Formal standard setting by the government has been seen as slow and inefficient, which can be a significant handicap if standards affect the pace of innovation.

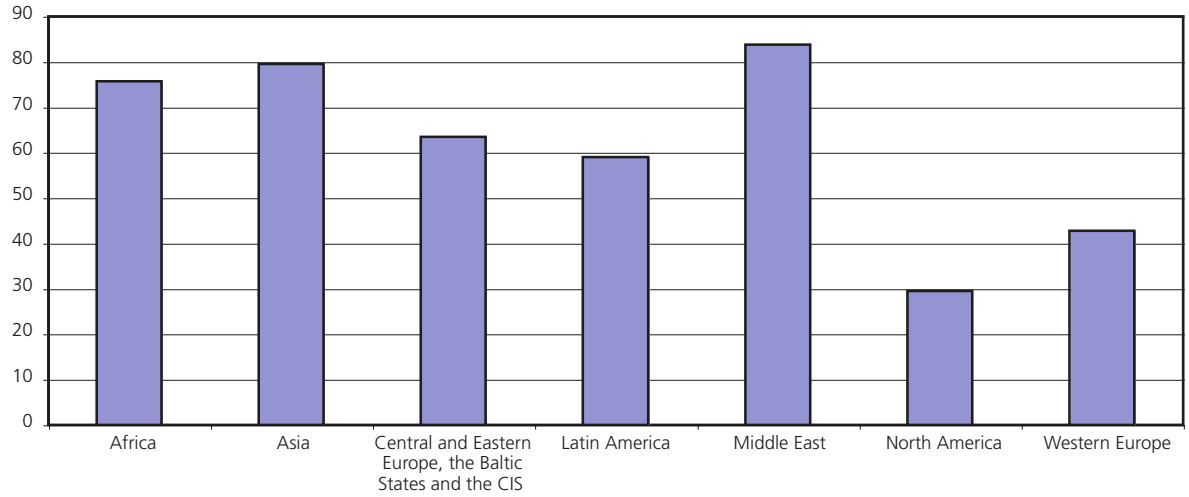
In practice, the separation between public and private standard setting is not always clear-cut. As has been seen, the organization of the process of standardization varies widely across countries. In general, regulations concerning safety, health and the environment are issued by governments. Often, however, the specific measures that satisfy the objectives of government regulations are spelled out in technical standards developed by private organizations. In European countries, the government refers to the privately developed standards in regulations. In the United States, local authorities, which typically lack the technical resources necessary to formulate the standards, often adopt privately developed standards.[77]

At the international level, the separation is similarly not well defined. ISO occupies a position between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries or are mandated by their governments. This would typically be the case in most developing countries where the national standardizing body has the legal status of a government department or a government statutory body.[78] On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. This would typically be the case in developed countries, where the standardizing body has the legal status of a private non-profit organization. Chart 7 shows the share of government subsidy in the total revenue of national standardizing bodies.

[77] See Casella (2001).

[78] See ISO Members Directory 2003. A recent survey of ISO Members in developing and transition countries conducted by ISO revealed that 86 per cent of those National Standards Bodies were governmental bodies.

Chart 7
Government subsidy in percentage of total revenue of national standardizing bodies, average by region



Source: ISO Members Directory 2003.

Producers play a leading role in the development of international standards but consumers have the possibility to influence the process. At the proposal stage, consumer participation depends on national provisions. As mentioned above, proposals for the development of new standards must be submitted to ISO through one of ISO's national members. In most countries applications for standardization are submitted by enterprises or groups of enterprises and accepted or rejected by technical committees based on various criteria. At the development stage, the technical committees which elaborate the standards comprise experts on loan from the industrial, technical, and business sectors which have asked for the standards, and which subsequently put them to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations, environmentalists, and so on. The experts participate as national delegations, chosen by the ISO national member for the country concerned.[79] In addition, since 1978, ISO has had a specialized Committee on Consumer Policy (COPOLCO). This Committee, as well as two others – on conformity assessments and developing country matters – have been created to provide strategic guidance on cross-sectoral issues to the technical committees, which by necessity are specialized and specific. Through its Committee on Consumer Policy, ISO undertakes to study how consumers can benefit from standardization, to promote consumers' input into the development of standards, both nationally and internationally, to encourage the exchange of experience on standards work of consumer interest, and to channel consolidated views from consumers both on current projects and on proposals for new work in areas of interest to them.

The question of NGO participation arises at the national, regional and international levels. In the present context, NGOs can be defined as non-profit organizations that operate independently of government or business structures and have non-commercial objectives related to environmental, consumer interest or sustainable development.[80] This Subsection focuses on the participation of all NGOs other than non-governmental national standards bodies in the ISO standardization process. There are two main ways in which NGOs can participate in ISO work, which are not mutually exclusive. First, they may be allowed or requested to participate in national delegations. Rules and procedures for the participation of NGOs in national delegations are developed at the national level and differ country by country. Second, due to the decentralized nature of ISO' work, NGO participation is generally through direct participation in the technical committees as "liaison" organizations or, to a lesser extent, as experts acting in an advisory capacity. ISO currently liaises with approximately 600 international and regional organizations through its technical committees. Most of those are non-governmental bodies specializing in a specific technical field. Only 42 organizations, however, have a formal liaison organization (L-organization) status. Although L-organizations have no formal voting rights, technical committees are expected to seek full and formal backing of those L-organizations actively involved in the work.

79 As mentioned above, national member bodies indicate to ISO's Central Secretariat whether they intend to act as Participating or Observing members in Technical Committees.

80 ISO, NGO Task Group Report 2001.

Most of the 42 L-organizations are environmental and public interest NGOs registered with Technical Committee (TC) 207. ISO/TC 207, one of the largest technical committees, was created in 1993 to develop the ISO 14000 Environmental Management standards. Because TC 207 is one of the only technical committees which deals with issues of specific importance to environmental and public interest NGOs, it is the only technical committee to have experienced significant NGO demand for improved procedures for NGO participation. In 2000, ISO/TC 207 created an NGO Task Group to examine the role of NGOs in the technical committee and the barriers to their effective participation.[81] The Task Group, which operated from 2001 to 2003, produced a list of 14 recommendations.[82]

A recent study by Morikawa and Morrison analyses available information on stakeholder participation in TC 207. The analysis fails to detect any meaningful effects of the various initiatives in terms of increased NGO attendance at TC 207 annual plenary meetings. Over the last seven years, industry, standards organizations, and consultants/registrars have been the major participants in these meetings, whereas NGOs were consistently the least represented stakeholder group at every plenary meeting.

Based on a review of relevant documentation and interviews, Oberthür et al. (2002) assessed the participation of NGOs in ISO and other international environmental organizations. Regarding the impact of NGO participation, they conclude that "[E]nvironmental NGO (ENGO) participation in TC 207 has had a discernible impact in a number of areas where the support of the ENGO community is required in order for the relevant standard to be effective. For example, in the context of environmental labelling, interviewees noted that ENGOs had been effective in reorienting the objectives and language of the relevant standards to reflect community value and concerns. In this context, ENGOs have had relative bargaining power because TC 207 members recognize that their support is required to make the standard effective and that they are in a position to develop their own set of standards that will compete with the ISO product. [...] Interviewees noted that ENGOs have had a lesser impact in areas that have a direct impact on industry operations, such as environmental management systems."[83]

Broad participation is also encouraged in the three SPS-related international standard-setting organizations as well as in some of the regional standardization bodies. Representation in the Codex is on a country basis. Delegations may include representatives of industry, consumers' organizations and academic institutions. A number of inter-governmental organizations, including the WTO, and international NGOs also attend in an observer capacity. Although they are "observers", the Codex Alimentarius Commission traditionally allows such organizations to comment at every stage except in the final decision, which is the exclusive prerogative of member governments. The Codex Executive Committee which acts as the executive organ of the Commission is composed of a chairperson, three vice-chairpersons and seven regional representatives (Africa, Asia, LAC, Europe, Near East, North America and South-West Pacific).[84] OIE Specialist Commissions comprise members experienced in veterinary science and regulatory issues, elected by the OIE International Committee and drawn from all OIE regions. The OIE increasingly seeks expert advice from outside government, including individuals and expert groups from industry, academia and government. Participants in IPPC expert working groups are phytosanitary experts nominated by countries or regional plant protection organizations and accepted by FAO for their individual expertise. The IPPC secretariat also seeks to ensure that experts are nominated and selected from different geographic regions. Participants in Interim Commission on Phytosanitary Measures (ICPM) business meetings and consultations are nominated by governments. IPPC Expert Working Groups do, at times, seek outside expertise from industry or academia to aid their deliberations.

81 The NGO Task Group produced two documents: The Guide to NGO Participation in TC 207 and the N590 document entitled "Increasing the effectiveness of NGO participation in ISO TC207".

82 See ISO document N590.

83 Oberthür et al. (2002), p. 174.

84 The technical/scientific input for Codex standards comes from the FAO/WHO Joint Expert Committee for Food Additives, the FAO/WHO Joint Expert Meeting for Pesticide Residues and a new joint body for microbiological contaminants. These are comprised of experts nominated by countries and chosen on their own merits by FAO/WHO, and can include governmental or NGO experts plus observers.

European standards are drafted by experts in specific fields, but industry, trade federations, public authorities, academia and NGO representatives are invited to contribute to the standardization process. The usual route for participation is through the National Standards Bodies. These Bodies have a duty to send balanced delegations to represent the national interest in a standardization project. Interest groups organized at the European level – representing environmentalists, consumers and small and medium-sized enterprises amongst others – also have the opportunity to contribute to the development of standards. Moreover, once the draft of a European Standard reaches a mature stage, it is released for public comment.

Participation in less formal standardization processes is variable. On the one hand, market processes creating de facto standards are closed. They clearly do not involve the direct and explicit participation of governments or consumers. As explained in Section IIB above, the economic literature has shown that under this kind of process there is almost invariably one winner, so there is an element of natural monopoly and thus a risk of market failure.

(d) Participation of developing countries in international standard-setting

A priori, both the demand for standards and the capacity to develop standardization infrastructure and activities depend to a large extent on factors correlated with a country's level of development. Demand for network externality standards (compatibility/interface) that emanates from producers clearly increases with the level of industrialization and development of the country. Similarly, demand for information asymmetry standards and environmental standards, tends to increase with the level of income and development. On the supply side, setting up a full fledged standardization infrastructure with all the responsibilities generally assigned to such infrastructure is very costly and takes time, and without much involvement from the private sector, developing country governments bear all the responsibility. Standardization infrastructure in developing countries has thus often been non-existent or relatively basic. Where national standardizing bodies have existed, they have tended to be governmental, only weakly linked to markets and almost exclusively inward oriented.

For various reasons discussed in Section IIB, the importance of standards not only for developed countries but also for middle and low-income countries has clearly increased in recent years and at the same time, the approach to standardization has evolved. The role of international standardization in particular has become more significant. These changes have put pressure on governments in developing countries to reform existing standardization infrastructure or develop new infrastructure. The new approach to standardization requires standardizing bodies to focus on the development of voluntary rather than mandatory standards, to become more responsive to markets, to rely more heavily on international standards and to participate more actively in international standardization. The next Subsection considers some problems faced by developing countries in the area of conformity assessment, while this Subsection addresses issues in the area of standards development.

As part of an in-depth study of the problems faced by standardizers in developing countries, ISO conducted a survey of ISO members in 110 developing and transition countries.[85] The survey results, published in 2002, revealed the persistence of two related problems. First, only a minority of standards and technical regulations were based on international standards. In 70 per cent of respondent countries, more than half the standards were not based on international standards and in 61 per cent of the countries, more than half the mandatory technical regulations were not based on international standards. Second, the level of participation of respondent countries in international standardization work was still very low. Forty-two per cent of the respondent countries were not registered as members of any ISO technical committee and 52 percent of the respondent countries had not attended any meetings of these technical committees in the last two years. Forty-eight per cent of the respondent countries did not even follow the work by correspondence. The main reason given for low participation was lack of funds at both industry and standardizing body level and lack of awareness and expertise in standardization.

[85] Seventy-one per cent of the 110 ISO Members answered the questionnaire. See El-Tawil (2002).

Improving participation of developing countries in international standardization is crucial. This has been recognized for several decades and, as discussed below, numerous initiatives have been undertaken to improve the situation. From a WTO perspective, harmonization and international standards play a key role in the agreements aimed at ensuring that standards do not create unnecessary obstacles, but rather facilitate the conduct of international trade.[86] Low participation in international standardization is part of the reason why only few developing country standards are based on international standards. More generally, if the level of standards that is optimal for developing countries differs from the level that is optimal for developed countries, the level of the "harmonized" international standard will have to be negotiated and both parties should be represented in the negotiations.

Developing countries may not necessarily be interested in the development of every single international standard. Countries with only a narrow industrial production and export base for instance, are likely to have a stake in only a subset of all compatibility standards developed at the international level, at least in the short-run. In the case of information asymmetry standards, low income countries may again be interested in only a subset of all standards developed at the international level. One may also expect more interest in food and more generally agricultural standards than in industrial standards. Developing countries' participation should thus vary depending on the institutions and the committees. With this qualification in mind, the available evidence on regional participation in international standard-setting bodies is considered.

There are several sources of information on the level of participation of developing countries in international standardization work. Some information is readily available from the standardizing bodies themselves and has been used in various studies. Other studies have used surveys of standardizers or case studies. Morikawa and Morrison (2004), using information on participating members (P-members) in Technical Committees (TCs), which is readily available on the ISO website supplemented with information on the location of TC secretariats and chairmanships by region, largely confirm the finding of the ISO survey mentioned above that participation of developing countries is still generally low.[87] Information on P-members – the most influential actors in the ISO system – in TCs only provides a partial description of the level of participation. Other important dimensions would include participation in TC working groups, where standards are deliberated, actual attendance at ISO meetings, the number of delegates at those meetings, and whether the country plays a leadership role.[88]

Participation by ISO members in Technical Committees in which developing countries have a genuine interest provides a more detailed picture. Particular attention has been devoted to ISO Technical Committee 207, which was created in 1993 to develop the ISO 14000 Environmental Management standards. Using data on annual TC plenary meeting attendance over the period 1997 to 2003, Morikawa and Morrison (2004) show that Africa, South and Central America and Central and Eastern Europe are under-represented at TC 207 meetings compared to their share of P-membership. However they also show that, probably due to the fact that four out of seven meetings were hosted in Asian countries, Asia sent significantly more delegates than its P-membership share would suggest.

In a joint effort to assess the impact of past initiatives to improve participation in international standardization and to learn from experience, ITC and the Commonwealth Secretariat conducted a series of six case studies in various developing countries. The six selected countries are at different levels of development. Malaysia was selected to represent countries where institutions engaged in standardization activities are relatively well developed. Jamaica, Kenya, Mauritius and Uganda were chosen because they had already made some progress in establishing the framework. Finally, Namibia was selected as typifying countries where work on standardization is at a nascent stage. Participation in both the bodies producing standards used in SPS measures and those producing standards used in technical regulations was considered.

86 See the preambles to both the Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures.

87 See ISO website: Technical Committee List: http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeList.TechnicalCommitteeList.

88 See Morikawa and Morrisson (2004).

Several lessons can be drawn from the six case studies. First, more advanced countries like Malaysia are able to participate in the work at all levels in the international standardization organizations in which they have an interest. However, even such countries cannot participate in all the working groups or technical committees in which they have an interest. In general, the participation of all the countries in the case studies is limited to attending the meetings of the apex bodies of these organizations. Second, most of the countries in the case studies do not appear to have at present the expertise needed for participation in the work at the technical level on the formulation of standards. Thirdly, participation in standardization activities, particularly at a technical level, is greatly facilitated if industry and interested business firms assist the agencies responsible for participating in the technical work, by carrying out background research and analytical work. With regard to technical assistance aimed at improving developing country participation, these considerations suggest that actions at the national level are needed to complement action taken by the international standard-setting bodies. Moreover, simple funding of developing country participation is insufficient, as most countries lack the analytical and technical capacity to participate effectively.

Technical assistance

Improving the participation of developing countries in standardization activities at the international level ranks among the main priorities for technical assistance in the area of technical regulations and sanitary and phytosanitary measures.[89] However, developing countries' needs in this area are considerable. The entry into force of the WTO TBT and SPS Agreements in 1995 have created new challenges and opportunities for developing countries and brought to light the need for assistance. Article 12 of the TBT Agreement, for instance, recognizes that developing countries may face special problems, including institutional and infrastructural problems, in the field of preparation and application of technical regulations, standards and conformity assessment procedures. Members are therefore enjoined to provide technical assistance. More generally, public and private capacity in developing countries needs to be strengthened to protect human health, animal health, and the phytosanitary situation, and to gain and maintain market access in the presence of rapidly evolving official and commercial requirements in the major markets.

Sizeable financial resources have already been devoted by donor countries to provide assistance in this area. Several databases on TBT-related and SPS-related technical assistance have been established in the last decade by the international institutions with the help of donors. In the SPS area, the Standards and Trade Development Facility (STDF) was established to facilitate collaboration in enhancing the expertise and capacity of developing countries to implement SPS standards.[90] In the TBT area, the ISO Database of technical assistance projects in the areas of standardization and related matters was established in 2001 to promote coordination of standards-related technical assistance projects and to enhance effectiveness in the design and implementation of such projects.[91] These databases are complemented by other databases such as the WTO-OECD Doha Development Agenda Trade-Related Technical Assistance Capacity Building Database (TCBDB), the Trade-Related Technical Assistance Database and the Database of Technical Assistance Programmes of the Free-Trade Area of the Americas.

In an effort to assist developing countries in their participation and use of international standards, ISO have approved a 2005-2010 Action Plan. This plan consists of workshops on various aspects of international standards development and the use of those standards as the basis for building internationally recognised technical infrastructures. In-country and regional training will be undertaken to assist developing countries that wish to take up chairmanships and secretariats for the international technical committees that develop international standards. There is also an emphasis on the physical resources and human resource knowledge required to effectively use the information technology that is now employed as the basis for standards development. Box 10 provides information on technical assistance relating to sanitary and phytosanitary measures.

89 See ITC and Commonwealth Secretariat (2003).

90 See http://stdfdb.wto.org/

91 See WTO document G/TBT/W/207 for an overview of the existing databases on TBT related technical assistance.

Box 10: SPS-related technical assistance

Increasing awareness among governmental officials in developing countries and helping answer SPS Agreement implementation questions is a key objective of WTO technical co-operation activities. Such assistance typically takes the form of national seminars and regional workshops targeted at SPS practitioners in developing countries. For regional activities, WTO also harnesses the particular expertise of the three standard-setting organizations by inviting lecturers from the OIE, IPPC and Codex to these activities. Since 1999, SPS technical assistance activities organized by the WTO Secretariat have included 35 regional and 34 national workshops.

Because the Codex, OIE and IPPC develop the standards that are recognized by the SPS Agreement, participation in the meetings and deliberations of these organizations is critically important to ensure that the standards developed reflect international consensus. To enhance the participation of developing countries in standards-setting meetings and activities, in training programmes and in regional technical consultations on standards and their implementation, the Codex, OIE and the IPPC have established trust funds. Contributions by donor agencies and member countries are expected to support these trust funds. The OIE provides financial support for the participation of Chief Veterinary Officers of its member countries in OIE standards-setting activities. Similarly, although funding for the travel and subsistence of participants in IPPC business meetings is normally the responsibility of national administrations, in the past the IPPC secretariat has ensured that funds are available for developing country participants before organizing such meetings.

All three organizations have developed training programmes, including conferences, seminars and workshops, to enhance national capacities on matters covered by the SPS Agreement. Computerized training resources also help address some of the training needs of member countries. For example, the FAO and the WHO have developed a CD-ROM training package that provides guidance to member countries on how to implement risk analysis principles in relation to food safety. The IPPC developed a diagnostic tool, the Phytosanitary Capacity Evaluation (PCE), to help countries address their current capacity and identify needs for assistance. The PCE is available on CD-ROM and can be downloaded from the IPPC website. The PCE has contributed to the establishment of baseline information for gauging the capacity gaps between the current phytosanitary situations and what would be needed to meet international standards requirements.

2. CONFORMITY ASSESSMENT

(a) Introduction

As was seen in the Section IIB, exporters may be required to adapt their production to conform to a standard in the importing country (thus, producing a number of different varieties of the same product in smaller batches for each market). Or they may be able to produce to a harmonized standard that is used both in their own and in the importing market or in several importing countries. Or else they may be able to manufacture a product in accordance with domestic requirements that are considered equivalent in the importing country. Each of these scenarios has different cost and efficiency implications. Yet there is an additional cost component common to all. In many cases, authorities in the importing country or importers themselves are not willing exclusively to rely on foreign manufacturers' own declarations or reports/certifications by foreign third parties that the required specifications have been met. Whatever the standard might be – national, harmonized or recognized as equivalent – assurance of compliance may be sought from domestic bodies in the importing country.

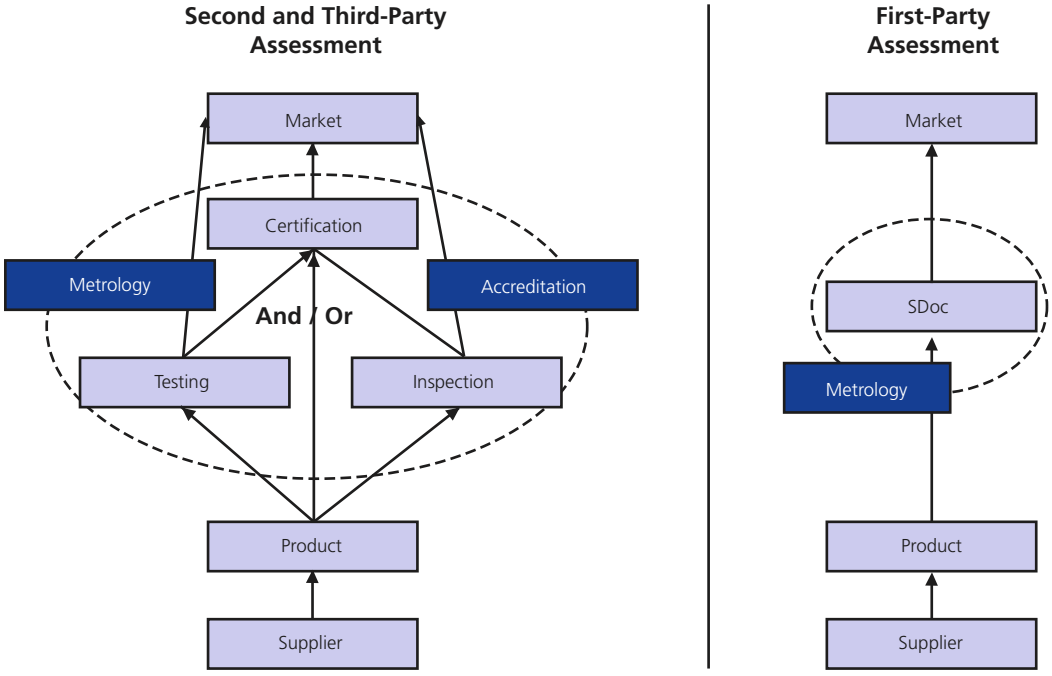
Clearly, this can result in an unnecessary obstacle to international trade if foreign providers possess the competence to give the required level of assurance in a cost-effective manner. As argued earlier, attestation of conformity with a standard should be carried out only once in the most cost-effective manner and, subsequently, be recognized everywhere. A complex network of institutions has developed over time to establish trust in the competence of foreign conformity assessment activities. The "architecture" of compliance control that is relevant for international trade is now examined. What steps are involved in developing a "chain of confidence" from the supplier in the exporting country to the buyer/government in the importing country? How are testing laboratories, inspection bodies and certification institutions in different countries and regions organized, and how can international recognition of conformity assessment results be obtained? What role do accreditation and international standards on conformity assessment play in this regard?

The different types of institutions that make up the technical infrastructure of conformity assessment will first be considered. Then a look will be taken at the number of existing conformity assessment systems at the regional and global level, before illustrating that the way conformity assessment is organized by different countries can affect international trade and lead to the negotiation of mutual recognition agreements (MRAs).

(b) Types of conformity assessment

The infrastructure of conformity assessment is multidimensional. Different means of determining a product's compliance with technical specifications feed into one another, are combined in various ways and involve a variety of actors at the national and international levels. In a narrow sense, conformity assessment refers to testing, inspection and certification as well as a supplier's declaration of conformity – that is, activities that deal with the characteristics of the product itself and that are of direct concern to the buyer and supplier. However, a wider definition includes the areas of metrology, which is an important prerequisite for the proper conduct of all other forms of conformity assessment involving measurements, and accreditation (the evaluation of the competence of any institution involved in conformity assessment). The latter activities are demanded by conformity assessment bodies in order to accord recognition for the quality of the services provided.

Chart 8
The technical infrastructure of conformity assessment



A supplier's declaration of conformity is made on the basis of a self-assessment by the supplier (although data may be obtained also from testing and inspection bodies) and is therefore referred to as first-party assessment. Second-party assessment is carried out by the purchaser or by testing/inspection bodies on his behalf. Third-party assessment must be independent of both the supplier and purchaser. This is always the case for certification bodies and may be the case for testing/inspection bodies if these are hired by a certification body or regulator. An overview of conformity assessment types and activities is given in Chart 8. Each activity will be further discussed below.

Testing and inspection

The main technique to determine the characteristics of a product is the testing of individual specimens or samples. Testing is often undertaken by specialized laboratories involving the use of sophisticated instruments. Its results only apply to the sample tested and usually cannot be extended to the whole product batch. A related form of assessment – often combined with it and not always clearly distinguished from testing – is the inspection of products, usually by visual means or simple instruments, such as scales. With the expansion in commercial relationships around the globe and the increased complexity of products, inspection activities carried out by specialized third-parties have flourished (ISO, 1998). Inspection relies heavily on the subjective judgement and experience of the inspector, whereas testing generally is carried out according to objective and standardized procedures by highly trained staff. Both inspection and testing may be performed by the manufacturer, the customer, regulatory authorities or by commercial service organisations hired on behalf of any party (ILAC, 1996). Depending on the type of tests/inspection carried out, commercial bodies may be held liable for their reports on the products examined.

Certification and quality systems registration

Certification goes beyond testing and inspection in several respects. Processes or product characteristics are assessed against a specific standard, whether mandatory or voluntary, which is not necessarily the case for testing and inspection. A formal attestation ("certificate") that the product meets the required standard or customer specifications (beyond the inspection or laboratory test reports) is provided and/or the right to use a certification mark on the product/packaging is licensed to the producer. Certification gives additional confidence on account of the systematic intervention of a competent third party that is always independent of either the purchaser or the manufacturer (WSSN, 2004). This is particularly important when the seller or buyer wishes to communicate compliance with a standard to a larger public or governmental authorities, for instance, in response to health and safety concerns. Certification bodies normally have expertise in specific product areas and use inspection, testing, evaluations of manufacturer's quality management systems and combinations of those activities in order to "both assess samples of the product and ... monitor production. ... [A] certification body may also periodically retest samples of product purchased in the market. ... Certification bodies may engage external inspection bodies and laboratories or use their own resources to provide inspection and testing facilities" (ILAC, 1996: 7). In other words, certification institutions are further characterized by the fact that, typically, they employ not only their own technical facilities, but also the services of external laboratories and inspection resources. They also provide for ongoing surveillance and, in case deficiencies are uncovered, may revoke their certificate/mark.

Certification is often based on type approval and not on 100 per cent testing of every individual item.[92] Consequently, liability for failure of certified products is not normally accepted by those bodies. In order for a certification body to reach more widespread recognition – which is the case, for instance, for Underwriters Laboratories in the United States and its "UL" mark – a lot depends on its perceived expertise and actual track record. Given that a reputation builds slowly, but is quickly destroyed, many certification bodies, when licensing foreign manufacturers to use their mark, at most delegate on-site inspection to a body located in the country of manufacture, but almost always require the necessary testing to be carried out under its direct control or supervision and in its own country (ILAC, 1996).

[92] ISO has identified eight commonly used certification types, most of which relate to type testing in combination with other elements, such as market or production surveillance or assessment of quality systems. There is also one type relating to assessment and surveillance of quality systems only, another to batch testing, i.e. of a statistical sample, and the final type is 100 per cent testing (ISO, 1998).

Aside from certifying product characteristics, certain bodies also attest to the conformity of systems, for example, an organization's quality management system to the relevant model of the ISO 9000 series of management system standards. This activity is referred to as quality systems "registration". Proper quality control mechanisms are expected to reduce production errors and, hence, variations in product quality. This implies that the actual compliance of any individual product with the required technical specifications cannot be guaranteed, but that the likelihood of defective elements within a product type is minimized. Periodic audits are carried out by the independent registrar in order to ensure that a registered quality system continues to deliver products of consistent quality with minimal variation. Quality systems registration is a rather practical form of assurance in recurrent high-volume transactions, such as those between manufacturers and suppliers of inputs. Once a sample of the required input has been approved by the manufacturer (or a certification body) or co-designed by the purchaser and supplier, the customer should be confident that the same quality can be reproduced consistently if the supplier's quality system is registered according to a recognized standard.

Supplier's declaration of conformity

Instead of a second-party or independent third-party verification of conformity, it may sometimes be sufficient if a supplier gives written assurance that a product conforms to specified requirements (ISO, 1996). "Supplier" must be understood broadly to refer to either the manufacturer or else distributor, importer, assembler etc. (ISO, 1998), whoever may be held responsible for placing a product on the market. The declaration should be based on either the supplier's own testing and inspection or the results of third-party institutions. It may have a specific format mandated by law in order to ensure that, based on the information provided in the declaration, recourse can be taken by the purchaser under the importing country's product liability laws. Supplier's declarations are not normally admissible in areas where defective products pose serious health, safety or environmental risks.[93] Other factors may be considered by governments in addition to the nature of the risks involved, such as the particular characteristics and the infrastructure of a given sector. In the United States, for instance, supplier's declarations of conformity are used for motor vehicles and motor vehicle equipment despite the high risk inherent in the sector (WTO Secretariat, 2005b). Other product categories allowing for supplier's declaration of conformity, which have been brought to the attention of the Committee on Technical Barriers to Trade (TBT) by various WTO Members, include disposable lighters, electrical products, electromagnetic compatibility (EMC) and telecommunication terminal attachment equipment (TTE), electronic safety equipment, electronics, equipment for use in potentially explosive atmospheres, machinery, medical devices, personal computers (PCs) and PC peripherals, personal protective equipment, recreational crafts, steel profiles for power transmission towers, telecommunications, toys, vehicle catalysts and vehicular natural gas (WTO Secretariat, 2005b).

Metrology

Of crucial importance for establishing confidence in any measurement results are the use of appropriate techniques and correct calibration[94] of testing or inspection instruments. Calibration ensures "traceability" of results to a reference standard with stated uncertainties in the level of precision. Usually, traceability involves a "chain of comparisons" by means of which measurement results are related to successively higher levels of reference standards and, ultimately, to a "primary" standard.[95] Such tasks are carried out by metrology

93 The perception of risks in a given sector may vary by country.

94 Calibration refers to the determination of metrological characteristics of an instrument through direct comparison to a standard. The calibration report specifies the relationship between the values indicated by a measuring instrument and the corresponding values realized by the standard. It therefore provides an indication of the accuracy and reliability of the instrument and of its consistency with other measurements. Based on the precision that may be obtained, the instrument can be considered "fit" for certain applications while not being suited for others (EUROMET, 2000).

95 For instance, the meter is defined as the length of the path travelled by light in a vacuum during a time interval of 1/299792458 of a second. It is realised on the primary level – i.e. by a National Metrology Institute or a specifically designated laboratory – by the wavelength from an iodine-stabilised helium-neon laser. Of course, other laboratories will not determine a "meter" with this type of laser. At lower accuracy levels, material measures like gauge blocks are used. The accuracy loss needs to be known in order to determine the suitability of a gauge block for certain measurement tasks. In this case, traceability is commonly established by using optical interferometry to determine the length of the gauge blocks with reference to the above-mentioned laser light wavelength (EUROMET, 2000).

institutions, such as calibration laboratories. Their work underpins all other forms of conformity assessment, as the adequate functioning of measurement instruments and their proper use by conformity assessment bodies are key elements in building confidence in the work of those organizations.

Accreditation

An organization performing any of the functions described above may seek to record its competence in a given field on a more permanent basis. This is achieved through accreditation with an authoritative body giving formal recognition of the competence of an organization to carry out specific tasks.[96] Accreditation is particularly important when users, be it regulating authorities or purchasers/suppliers, are not in a position to evaluate themselves the competence of a conformity assessment provider. This may be due to the technical complexities involved and, additionally, in international trade due to the spatial separation between a conformity assessment body in the exporting country and the importer. Accreditation bodies are always independent of both the supplier and the purchaser of a product.

Accreditation bodies must have first-class technical expertise although they do not themselves deal with verification of product specifications. Their task is to rate the organizations carrying out such functions. Usually, a set of good practices are provided or endorsed by an accreditation institution of how a testing, inspection or other body is supposed to conduct its business. In order to be accredited, adherence to such guidelines must be demonstrated. While accreditation bodies have their own assessors and may employ additional expertise from external sources to gather information on the competence of applicant institutions, part of the underlying facts are usually collected via peer assessment.[97] Depending on the country, accreditation of testing facilities, calibration laboratories, inspection bodies and quality system/product certification bodies is undertaken by specialized accreditation bodies or a single organization. Accreditation is commonly seen as a governmental responsibility or, at least, as requiring endorsement by the government, whereas inspection, testing, certification, etc. in many parts of the world are mostly commercial activities.

Accreditation of laboratories has the longest tradition, as the availability of objective and accurate test data is an essential element in compliance control that "underpins much of the value of the other [forms of conformity assessment]. ... Laboratory accreditation organizations ... evaluate laboratories against quality system elements but also use peer assessors to evaluate specific technical competence taking into account the technology involved, the particular test methods to be covered and the skills required of individuals working in the laboratory. Accreditation is granted to laboratories for specific products or specific test methods or both" (ILAC, 1996: 8-9). Many laboratory accreditation entities have extended their scope to include inspection bodies as well. Accreditation organizations for product or quality systems certification bodies or both are a relatively recent phenomenon. Here, accreditation testifies to the competence of the certification body in verifying the properties of a product as well as the transparency of its operations.

(c) Harmonization of conformity assessment and international and regional systems

A well-functioning technical infrastructure at the national level does not automatically lead to "one-stop conformity assessment" in world trade. Confidence in the work of conformity assessment bodies in other countries needs to be established through multilateral cooperation. To that end, a variety of international and regional fora have been established, most notably at the accreditation level. Their main objective is to facilitate mutual recognition agreements (MRAs) between members, i.e. the acceptance of conformity assessment results obtained by foreign bodies. Harmonization in the area of conformity assessment is crucial in order to facilitate such efforts and, hence, reduce the duplication of assessments in different countries.

[96] As was stated in the introduction, accreditation institutions are sometimes not considered to be conformity assessment bodies as such, as they necessarily have to be an "outsider" in order to perform third-party attestation of the competence of conformity assessment bodies. Accreditation is, however, listed as a conformity assessment activity in the TBT Agreement. Similar divergences of views exist in regard to calibration and other metrology activities that are a prerequisite for carrying out various types of conformity assessment. See, for instance, ISO (2004). These kinds of nuances are not relevant for the purposes of this report.

[97] Sometimes accreditation and peer assessment are portrayed as alternatives.

Harmonization

The international standards/guides on conformity assessment, developed most notably by the ISO Committee on Conformity Assessment (CASCO) in conjunction with representatives of the IEC, seek to establish unified principles that, if followed by a conformity assessment body, increase the confidence that users can have in its competence. These principles are largely process-oriented. They establish best practices that require conformity assessment bodies to be consistent and transparent in their operations and candid about their actual competence. This represents an important difference from ISO or IEC standards on products, for instance, which contain detailed technical specifications that are often directly built into national regulations. There are guides for each field of conformity assessment, which have been or are in the process of being transposed into international standards in the ISO/IEC 17000 series, i.e. converted into more prescriptive documents establishing clear "checklists" of criteria to be fulfilled (see Table 6).

Table 6
List of CASCO guides and standards

List of CASCO guides and standards by field of application		
Vocabulary, principles and common elements of conformity assessment	**ISO/IEC 17000**: 2004	Conformity assessment - Vocabulary and general principles
	ISO PAS 17001: 2005 Final Draft PAS approved, due to be published by end of June 2005	Conformity assessment - Impartiality - Principles and requirements
	ISO PAS 17002: 2004	Conformity assessment - Confidentiality - Principles and requirements
	ISO PAS 17003: 2004	Conformity assessment - Complaints and appeals - Principles and requirements
	ISO PAS 17004: 2005 Final Draft PAS approved, due to be published by end of June 2005	Conformity assessment - Disclosure of information - Principles and requirements
	ISO PAS 17005: 2005 Final Draft PAS approved, due to be published by end of June 2005	Conformity assessment - Use of management systems in conformity assessment - Principles and requirements
Code of good practice for conformity assessment	**ISO/IEC Guide 60**: 2004	Conformity assessment - Code of good practice
Writing specifications for use in conformity assessment	**ISO/IEC Guide 7**: 1994	Guidelines for drafting of standards suitable for use for conformity assessment
Testing/calibration	**ISO/IEC 17025**: 2005 (Awaiting publication due in May 2005)	General requirements for the competence of testing and calibration laboratories
	ISO/IEC Guide 43-1: 1997 Reconfirmed in 2002	Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes
	ISO/IEC Guide 43-2: 1997 Reconfirmed in 2002	Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies
Inspection	**ISO/IEC 17020**: 1998 Reconfirmed in 2002	General criteria for the operation of various types of bodies performing inspection
Supplier's Declaration of Conformity (SDoC)	**ISO/IEC 17050-1**: 2004	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
	ISO/IEC 17050-2: 2004	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation
Product certification	**ISO/IEC Guide 23**: 1982 Reconfirmed in 2003	Methods of indicating conformity with standards for third-party certification systems
	ISO/IEC Guide 28: 2004	Conformity assessment - Guidance on a third-party certification system for products
	ISO/IEC Guide 53: 2005	An approach to the utilization of a supplier's quality system in third-party product certification
	ISO/IEC Guide 65: 1996 Reconfirmed in 2000	General requirements for bodies operating product certification systems
	ISO/IEC Guide 67: 2004	Conformity assessment - Fundamentals of product certification

Table 6
List of CASCO guides and standards (cont'd)

List of CASCO guides and standards by field of application		
System certification	**ISO/IEC Guide 62**: 1996	General requirements for bodies operating assessment and certification/registration of quality systems
	ISO/IEC Guide 66: 1999	General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS)
Certification of persons	**ISO/IEC 17024**: 2003	General requirements for bodies operating certification of persons
Marks of conformity	**ISO Guide 27**: 1983 Reconfirmed in 2003	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
	ISO/IEC 17030: 2003	General requirements for third-party marks of conformity
Accreditation	**ISO/IEC 17011**: 2004	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
Mutual Recognition Arrangements (MRAs)	**ISO/IEC Guide 68**: 2002	Arrangements for the recognition and acceptance of conformity assessment results
Peer assessment	**ISO/IEC 17040**: 2005	Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies

List of CASCO projects under way		
Writing specifications for use in conformity assessment	**ISO/IEC Guide 7**: 1994 New Work Item Proposal for revision of ISO/IEC Guide 7 expected in early 2005	Conformity assessment - Guidelines for drafting specified requirements suitable for use for conformity assessment
System certification	**ISO/IEC 17021** [CASCO WG 21] Revision of Guide 62:1996 and ISO/IEC Guide 66:1999, with the new standard being applicable for audit and certification of all types of management system. DIS vote approved on ISO side but not IEC side. Will be released for 5-month DIS2 ballot by June 2005	Conformity assessment - Requirements for bodies providing audit and certification of management systems
Sector specific *Greenhouse Gases*	**ISO 14065** [Joint CASCO-ISO/TC 207 WG 6] WD prepared and will released for a CD consultation after the next WG meeting in March 2005	Greenhouse gases - Requirements for validation and verification bodies for use in accreditation and other forms of recognition

Source: ISO Communication QS-CAS-PROC/13, March 2005.

The relevant ISO/IEC standards require certification bodies to operate in a non-discriminatory fashion, i.e. be accessible to any applicant, to be impartial and free from any commercial, financial or other pressures which might influence the results of the certification process, to safeguard the confidentiality of information provided by applicants, and to have appropriate procedures in place to deal with appeals, complaints and disputes brought by any party involved. Further details are provided on what type of information should be gathered and how the assessment team should conduct its work to observe due process, including in post-certification surveillance. The body must fulfil certain legal requirements to ensure control over the use of certification marks and prevent misleading use (Fukuda, 1999). Similar requirements are specified in the respective documents for accreditation bodies.

ISO/IEC standards for testing laboratories and inspection bodies contain both "management" requirements of a more organizational nature and technical requirements stipulating proper documentation of calibration methods and method validation, equipment, measurement traceability, sampling methods etc. However, even the latter requirements are kept sufficiently general to ensure best practice, while giving leeway to the

individual institution to apply specific methods. A stylized example of how ISO testing standards may be applied in practice is provided on the ISO webpage: "A major manufacturer regularly orders large supplies of raw materials from overseas countries. Before the materials are shipped, samples are analysed by local testing laboratories to confirm that they conform to grades stipulated in the contracts between the manufacturer and its suppliers. As the contracts refer to grades defined in internationally agreed ISO standards, there is less room for error and disagreement. The analyses themselves are carried out according to ISO test method standards and the organizational processes of the local laboratories conform to another ISO standard giving the general requirements for the competence of testing and calibration laboratories."[98]

International and regional systems

A number of international and regional systems have developed over time with the objective of establishing networks of conformity assessment bodies whose competence can be relied upon by all members. Cooperation at the accreditation level has proven particularly important in order to minimize the number of bilateral coordination efforts that confidence-building in another country's conformity assessment infrastructure would otherwise require. If agreement between accreditation organizations is reached, certificates from all certification bodies or test results from all laboratories accredited in one country are accepted by the other signatories without the need for further contacts at the level of certification or testing bodies. Of key importance in facilitating multilateral MRAs between accreditation bodies are the International Laboratory Accreditation Cooperation (ILAC), which operates as a forum for accreditors of laboratories and inspection bodies, and the International Accreditation Forum (IAF), which fulfils this function for accreditors of certification bodies (ISO, 1998). ILAC and IAF seek to assist in creating and multilateralizing MRAs among its members. IAF has managed to establish a "multilateral" MRA among a range of its members with the help of regional groupings, such as the European co-operation for Accreditation (EA) and the Pacific Accreditation Cooperation (PAC), and ILAC has developed a "global" MRA among all its 46 full members.[99] The latter arrangement promotes usage of ISO/IEC standards and guides relevant to accreditation, since the acceptance of each member's accreditation work is facilitated if common procedures are followed and reliable documentation provided in accordance with internationally agreed requirements.

The ILAC Mutual Recognition Arrangement, for instance, specifically requires that each signatory accreditation body maintains conformity with ISO/IEC Guide 58 ("Calibration and Testing Laboratory Accreditation Systems – General Requirements for Operation and Recognition") and ensures that all accredited laboratories comply with ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories") (ILAC, 2004). The arrangement has been built upon existing regional arrangements. Each "recognized Regional Cooperation Body" is responsible for maintaining the necessary confidence in accreditation bodies from their region. Currently, the European co-operation for Accreditation (EA) and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) are the only regions whose MRAs and evaluation procedures are recognized by ILAC. The Inter-American Accreditation Cooperation (IAAC) and Southern African Development Cooperation for Accreditation (SADCA) are in the process of refining their MRA evaluation processes for future recognition by ILAC. Bodies that are not currently affiliated with a recognised region may apply directly to ILAC for evaluation and recognition. Continued confidence in the work of MRA signatories is ascertained through periodic peer evaluations undertaken by a team composed of other members.

In order to help members to establish and extend MRAs and to ensure that members only accredit competent and impartial conformity assessment bodies, ILAC and IAF also engage in a number of complementary activities. In particular, they provide their own documentation. Both ILAC and IAF produce guidance material for member organizations on how to apply relevant ISO/IEC standards, as well as guides and documents that address the operation of conformity assessment schemes in specific areas, such as ILAC Guide G7:1996 on "Accreditation Requirements and Operating Criteria for Horseracing Laboratories". In order to help accreditation bodies in their duty to periodically monitor the performance of accredited institutions and ensure their continued competence, ILAC has also developed a guide on proficiency testing programmes and assists members in their implementation, i.e. in holding inter-laboratory comparisons of test results obtained

98 See http://www.iso.org/iso/en/comms-markets/conformity/iso+conformity.html, accessed on 17 February 2005.

99 As at 2 February 2005. See at http://www.ilac.org, accessed on 17 February 2005.

from samples with properties known by the organizer. IAF has a programme in place to assist low and medium income economies to create their own accreditation bodies. Finally, both fora facilitate the exchange of information between accreditation bodies, undertake and coordinate training of assessors and other personnel, and liaise with other relevant institutions, such as ISO.

There are also cooperation arrangements between bodies in other areas of conformity assessment. For instance, the scheme for the acceptance of test reports dealing with the safety of electrical and electronic products (IECEE-CB Scheme) is a multilateral agreement among participating IEC member countries that allows the so-called National Certification Bodies, (NCBs, i.e. certification institutions designated by IEC members) to issue "CB Test Certificates" whenever a sample of electrical products has been tested and found to be in conformity with the relevant IEC standards by one of the almost 180 CB testing laboratories.[100] In other words, a manufacturer utilizing a CB test report issued by one of these organizations can obtain national certification in all other member countries of the CB Scheme. Participating developing countries include Argentina (2 CB test laboratories), China (16), India (13), the Republic of Korea, (3), Malaysia (1), and South Africa (1). Between laboratories and inspection bodies, arrangements sometimes take the form of pledges to subcontract each other on a reciprocal basis for tests of individual components of more complex items in international trade.

A lot of international collaboration is also going on in the area of metrology. The Inter-American Metrology System (SIM), for instance, unites national metrology organizations from all 34 member nations of the Organization of American States (OAS) with the objective of achieving equivalence among national measuring standards and calibration certificates issued by national metrology laboratories.[101] Given the interrelated nature of conformity assessment activities, MRAs at one level, say between different metrology institutions, may facilitate the conclusion of MRAs in the testing or certification area for sectors that depend strongly on precision measurement.[102]

Regional cooperation efforts often precede wider international engagement, not least since neighbouring countries may also be principal trading partners. In particular, regional coordination in the development of conformity assessment infrastructure may help to address in a cost-effective manner the problem of a complete absence or insufficiency of relevant institutions at the national level for some of the smaller or poorer countries in the region. Rather than each country attempting to have certification, inspection and testing facilities for all relevant sectors, countries in a region may seek to foster a network of laboratories with specialized skills and equipment. A regional accreditation system may contribute to forming such a network, while at the same time increase competition among laboratories with similar activity profiles to the benefit of customers. Since the technical competence of accredited facilities should be the same, customers will choose those offering the best value for money. Regional cooperation can also avoid duplication at the level of metrological reference standards and equipment, and thus increase traceability of measurement results.

Regional cooperation currently takes place in Europe, the Asia-Pacific region, the Americas and Southern Africa, and is mainly geared towards multilateral recognition of national accreditation bodies. In Europe, the EA, merged in 1997 from the European co-operation for Accreditation of Laboratories (EAL) and the European co-operation for Accreditation of Certification (EAC), comprises EU members. Members of EA are the nationally recognised accreditation bodies of the member countries or accession candidates of the European Union and EFTA. In order to be part of the individual multilateral recognition agreements (called "MLAs" by the EA and some other institutions) for either certification body, laboratory or inspection body accreditation, a peer evaluation must be passed successfully. The certificates and reports issued by organisations accredited by national accreditation bodies are then accepted in all the MLA countries. In addition, the signatories of each MLA have negotiated a number of bilateral agreements with accreditation bodies elsewhere. For instance, members to the EA Testing MLA have concluded bilateral recognition arrangements with NATA (Australia), IANZ (New Zealand), SANAS (South Africa), SAC (Singapore), INMETRO (Brazil), ISRAC (Israel), HKAS (Hong Kong, China) and AZLA (United States).[103]

100 See http://www.iecee.org, visited on 22 February 2005.

101 See http://www.sim-metrologia.org.br/whoweare/sm_whoweare.html, accessed on 22 February 2005.

102 There are many other equally important international initiatives, which cannot be discussed here.

103 See http://www.european-accreditation.org, accessed on 18 February 2005.

APLAC is open to laboratory accreditation bodies in any Asia Pacific Economic Cooperation (APEC) economy (and others if agreed by members). It is recognized by APEC member economies as a Specialist Regional Body, assisting with the work of the APEC Sub-committee on Standards and Conformance. The list of APLAC Members is almost identical to that of APEC, with the exception of Chile, Peru and Russia, which are members of APEC but have not yet applied for APLAC membership, and India, that is member of APLAC but is not an APEC member.[104] Similarly, the Pacific Accreditation Cooperation (PAC) operates as a forum for accreditation of certification bodies in the APEC region. Like the EA, APLAC and PAC seek to transform the existing network of bilateral agreements between members into multilateral arrangements. This is not always an easy task given the different levels of development in member countries. For instance, PAC's Multilateral Recognition Arrangement (MLA) for Accreditors of Product Certification Systems comprises only few members (JAS-ANZ (Australia and New Zealand), SCC (Canada) and EMA (Mexico)).[105] Both APLAC and PAC include developed and developing countries, with the former often providing support to raise technical competencies in the latter. For instance, Australia's National Association of Testing Authorities (NATA) provides a number of training programmes to other APLAC members.

Membership of the IAAC, which covers North America, most South and Central American countries, as well as some Caribbean island states, also comprises countries at different levels of development. A number of training activities and internship programmes with the more advanced members are regularly organized, for which additional funds are obtained from regional organizations (in particular the Organization of American States, OAS). IAAC's members are accreditation bodies for certification/registration bodies, inspection bodies and testing/calibration laboratories. Like in the other regional systems, members of IAAC's MLAs are required to demonstrate (through peer evaluations) conformity with pertinent ISO/IEC standards and guides (and related IAF or ILAC guidance documents) and conformity of all accredited bodies with the relevant ISO/IEC standards and guides. IAAC MLA members also regularly participate in the assessment/re-assessment and surveillance visits of conformity assessment bodies performed by other IAAC MLA member accreditation bodies.[106]

Similar to the other regional bodies, one of the principal goals of SADCA is to foster MRAs between qualifying institutions in SADC member countries. However, within SADCA, only South Africa and Mauritius currently have a national accreditation organization and, therefore, have taken on special leadership and training responsibilities in the meantime. Only three other countries have expressed the intention to establish their own national accreditation infrastructure (Gilmour and Loesener, 2003). In light of this, SADCA seeks to define a suitable accreditation infrastructure, enabling organizations in SADC member states to access accreditation services from recognised national accreditation bodies. It is also foreseen that a regional accreditation service, SADCAS, will be formed through which conformity assessment bodies can obtain region-wide accreditation directly. It is also hoped that SADCA activities will stimulate the creation of a pool of internationally acceptable accredited laboratories and certification bodies (for personnel, products and systems, including quality and environmental management systems) in the SADC region.[107]

(d) Conformity assessment and international trade

Conformity assessment is not a trade barrier as such. It is indispensable, since compliance with certain technical specifications may be mandated by either the government in the importing country or customers in order to ensure safety, quality or compatibility. The degree of flexibility that suppliers have to demonstrate conformity with required specifications has a direct impact on their cost competitiveness.

When demanding proof of conformity, customers will balance the benefits of higher levels of assurance against the practical or legal consequences of non-compliance they may suffer. If a supplier can easily be switched (and possible downtime costs for consumers of intermediate goods are low) or if the legal consequences or

104 See http://www.ianz.govt.nz/aplac/aboutaplac/about_general_info.htm, accessed on 18 February 2005.

105 See http://www.apec-pac.org/sections/pacmla/files/MLA%20Signatories%20-%20Product.doc, accessed on 18 February 2005.

106 See http://iaac-accreditation.org/Mla.html, accessed on 18 February 2005.

107 See http://www.sadca.org, accessed on 18 February 2005.

inconveniences for the buyer are minor and product liability claims against the supplier easy to enforce, a customer may be satisfied with a supplier's declaration of conformity, perhaps in connection with a certified quality management system. At the same time, a supplier may offer higher levels of assurance, for instance by having a batch of products tested by an accredited laboratory, if the additional costs are less than his expected gain in reputation or the costs of liability insurance.

Regulators usually require a minimum level of assurance, defined by law. Conformity with government-mandated specifications shall be the focus of this Section. Depending on the regulatory standard pursued, the government may require conformity assessment to be carried out by specific authorities or mandate the conduct of certain activities, such as 100 per cent testing, or even precise procedures (e.g. spraying of every good X with chemical detergent Y for Z amount of time). When only designated bodies are allowed to conduct the required conformity assessment procedures, a duplication of efforts or increased costs for exporters are a likely result. If exporters are free to choose conformity assessment institutions, government confidence in the body conducting the mandated assessment is a key issue. In order to avoid unnecessary barriers to trade, governments generally encourage cooperation between conformity assessment bodies and lend their support to mutual recognition efforts, sometimes through active involvement in MRA negotiations.

A level playing field between competitors, both domestic and foreign, is ensured if any product or service found to be in conformity with a given standard in one country may be put on the market in any other trading partner as well. The assessment of conformity with regulations may become a barrier to trade when products have to undergo unnecessary re-testing, re-inspection or re-certification in order to gain access to individual export markets,[108] or when prescribed activities/procedures are overly burdensome for foreign producers in order to reach a given level of assurance. Hence, the degree to which conformity assessment acts as a trade barrier hinges critically upon the flexibility provided to exporters in choosing conformity assessment providers, activities and procedures. But even if the importing country is rather flexible as to where and how conformity is demonstrated, transaction costs for foreign suppliers can be significant, depending on the availability and cost-effective provision of relevant conformity assessment services and their international recognition. Problems in relation to the first point vary with the stringency of underlying regulations and the level of risk associated with a product and tolerated by the importing country. Deficiencies in regard to the latter issues are primarily to be addressed by the exporting country and are related to its level of development, industrialization and diversification.

The degree of trade restrictiveness of conformity assessment requirements is a function of both elements combined. The factors in the exporting country that may influence the availability and international recognition of conformity assessment institutions, such as private or public sector provision of conformity assessment services will first be discussed. Then to what extent conformity assessment requirements by the importing countries can pose problems for exporters will be illustrated. The role of MRAs will be highlighted as well as the difficulties that may result from incompatibilities among national conformity assessment structures.

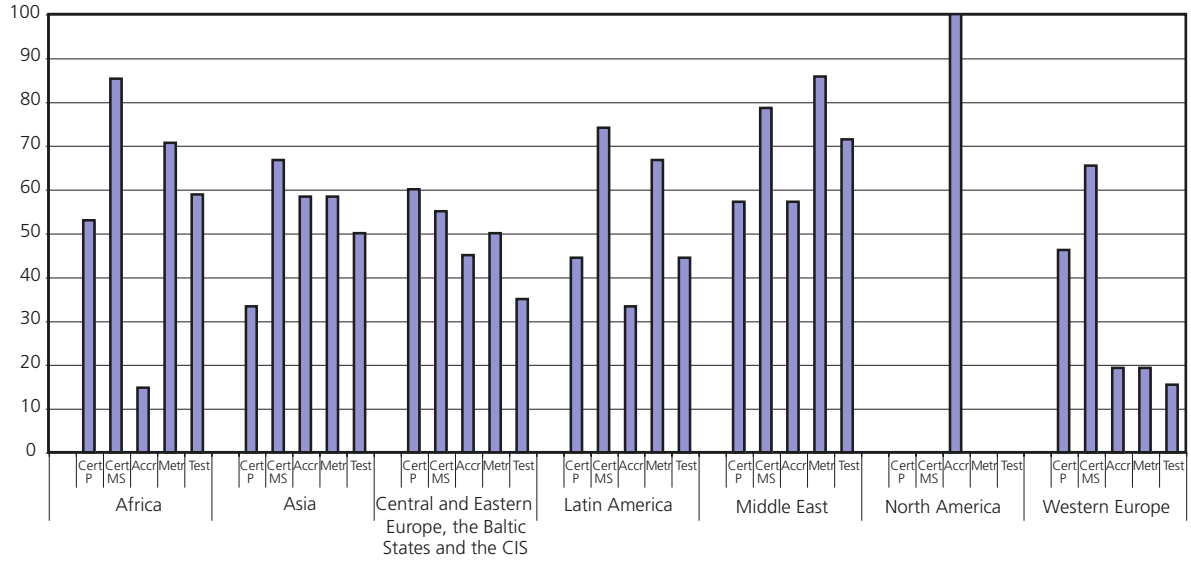
Provision of conformity assessment services and international recognition

In small developing countries, conformity assessment-related (and standards-related) activities are often centralized and government-driven. A single governmental organization may be responsible for writing standards, providing metrology services, certification and accreditation, and sometimes even testing facilities. Commercial provision of conformity assessment services may be low due to restrictive policies, the small size of the domestic market, high costs of inputs and scarce human resources. The availability of conformity assessment services then crucially depends on the human and financial resources at the disposal of the government and its awareness of the needs of exporters. For international recognition, centralized arrangements may cause problems if impartiality, objectivity, non-discrimination and avoidance of conflicts of interest, as stipulated by the relevant ISO/IEC standards on conformity assessment, are in doubt. From Chart 9 it can be seen that in Africa, the Middle East and Asia, and slightly less so in Latin America, the

[108] Of course, in individual cases, re-testing etc. in the importing country may be necessary, for instance, if potential environmental effects are directly related to the area where, say, an imported plant will be grown.

national standardizing body that is a member of ISO, also provides other conformity assessment services, most notably certification and metrology services. This stands in strong contrast with North America, where the standardizing body's additional activities are confined to accreditation. The low numbers on accreditation in other regions may also give an indication that, particularly in Africa, accreditation frequently does not exist at all at the national level. Finally, the comparatively small shares of standardizing bodies in the developed regions, North America and Europe, that also conduct testing activities supports the assumption that testing services are available from a variety of other sources.

Chart 9
Share of standardizing bodies conducting type of conformity assessment procedure



Source: ISO Members Directory 2003.

Accreditation bodies must have a degree of authority and, therefore, are normally government-owned or a private body with close affiliations to the government. According to Gilmour and Loesener (2003), in China, India, Japan, Jordan, Malaysia, Tunisia and the United States, accreditation is carried out by a Ministry. In Brazil, Colombia, Egypt, New Zealand and Singapore the national accreditation body is a Statutory Authority. In Argentina, Australia, Canada, Cuba, France, Mexico and South Africa accreditation is entrusted to a not-for-profit organization. Responsibility for accreditation may not always be as clear-cut as presented in this Report. In the United States, for instance, the accreditation system is both in public and private hands and continues to be highly decentralized: the Occupational Safety and Health Administration (OSHA), for example, accredits laboratories as competent to test and certify products used in the workplace and only accepts certification from accredited bodies as demonstrating compliance with its regulations. But there are also private accreditation programmes established by industry, such as the National Aerospace and Defense Contractors Accreditation Programme (NADCAP) that accredits laboratories and quality systems of suppliers in these industries (National Research Council, 1995).

Decentralized and private sector accreditation can pose a problem with many trading partners that understand accreditation as implying governmental involvement and authoritative and official decisions on the competence of accredited institutions. In order to facilitate mutual recognition, the National Institute of Standards and Technology (NIST), which is a federal agency within the US Commerce Department's Technology Administration, operates a programme to officially "recognize" private accreditors.[109] NIST also runs centralized accreditation programmes itself, such as the National Voluntary Laboratory Accreditation Programme (NVLAP). Although accreditation is voluntary and on a fee-basis, fulfilment of a number of regulations, for instance on asbestos, require testing by a NVLAP-accredited laboratory. The costs for laboratories to become accredited consist of one-off fees and recurrent payments both on an annual basis and, in addition, whenever on-site inspections are due. A laboratory wishing to be accredited for commercial

[109] This means that, in the United States, governmental "recognition" represents an additional level in the conformity assessment infrastructure "above" accreditation.

product testing is charged $4,030 annually, plus a $500 application fee in the first year. To this, variable on-site assessment fees must be added, ranging between $1,600 and $2,900 for some specifically identified products.[110] The fee structure is similar in other accreditation bodies, such as India's National Accreditation Board for Testing and Calibration Laboratories (NABL), which is an autonomous body under the aegis of the Department of Science and Technology of the Government of India and the sole accreditation body for testing and calibration laboratories. Here, a testing laboratory seeking accreditation for up to two product groups per field of testing pays a non-refundable application fee of Rs.10,000 and the same amount annually from the date of accreditation. Re-assessments must be carried out every three years at a rate of Rs.1,000-1,500 per day plus overhead charges of Rs.5,000.[111] The annual fee of Rs.10,000, for instance, converts to just $205 at the official exchange rate and to $1,136 in terms of purchasing power parity, which is still lower than the fees charged by NVLAP.[112] Both NVLAP and NABL are open to applications from foreign laboratories. They are also both signatories to the ILAC MRA, i.e. recognize each other's accreditation systems. As a consequence, test results from laboratories accredited by either one body should be accepted in both countries.

Where developing countries have not established a national accreditation body, domestic conformity assessment institutions must seek accreditation in individual export markets. If ILAC membership is taken as an indication of the availability of national accreditation bodies, developing countries in the Western Hemisphere are relatively well represented by Argentina, Brazil, Chile, Cuba, Ecuador, El Salvador, Guatemala, Mexico and Trinidad and Tobago. OAS (1996) and OAS (1997) also mention the existence of national accreditation bodies in Colombia, Costa Rica and Peru and plans for their establishment in Bolivia and Panama. A similar situation exists in developing Asia, where Hong Kong, China; China; Chinese Taipei; India; Indonesia; the Republic of Korea; Malaysia; Pakistan; the Philippines; Singapore; Thailand and Viet Nam have national accreditation bodies that are members of ILAC. Conversely, the lack of accreditation capacity in Africa is conspicuous, with only five countries (Egypt, Mauritius, Morocco, South Africa and Tunisia) featuring among ILAC members.

Testing laboratories or inspectors are normally for-profit service providers hired by clients (to verify conformity to stated specifications), suppliers (to cross-check against their own tests and support manufacturer's declarations of conformity with regulations) and other conformity assessment institutions, such as certification bodies, often for highly specialized tasks. Annual data collected by the US Bureau of the Census shows the importance of the testing laboratories services sectors (NAICS 54138) both in terms of size and rapid growth in recent years (see Chart 10). In the last two years for which data are available, the sector has grown around 11 per cent annually, generating more than $9 billion in revenues. These values largely underestimate the revenues generated in the third-party testing sector, as more testing laboratories are classified under engineering services. The growth of the third-party testing sector can also be expected to stimulate increased activities in the other layers of conformity assessment, both at the private end and as far as the need for government oversight is concerned.

Similar developments may be assumed to take place for inspection services. On-site/pre-shipment inspection is widespread in private business transactions, especially for low-value added bulk commodities, such as barley, maize, rice or wheat, where transport costs are substantial and refusal at the port of destination would result in important losses. This has given rise to the development of multinational inspection companies (increasingly also providing other conformity assessment services). For instance, the Société Générale de Surveillance (SGS) offers an on-site grain grading programme, which allows for continuous tracking of quality and quantities placed in different silos. These consistent, high-tech tracking operations are likely to make it easier to blend grains in accordance with the minimum contractual specifications and to be less costly at the time of loading

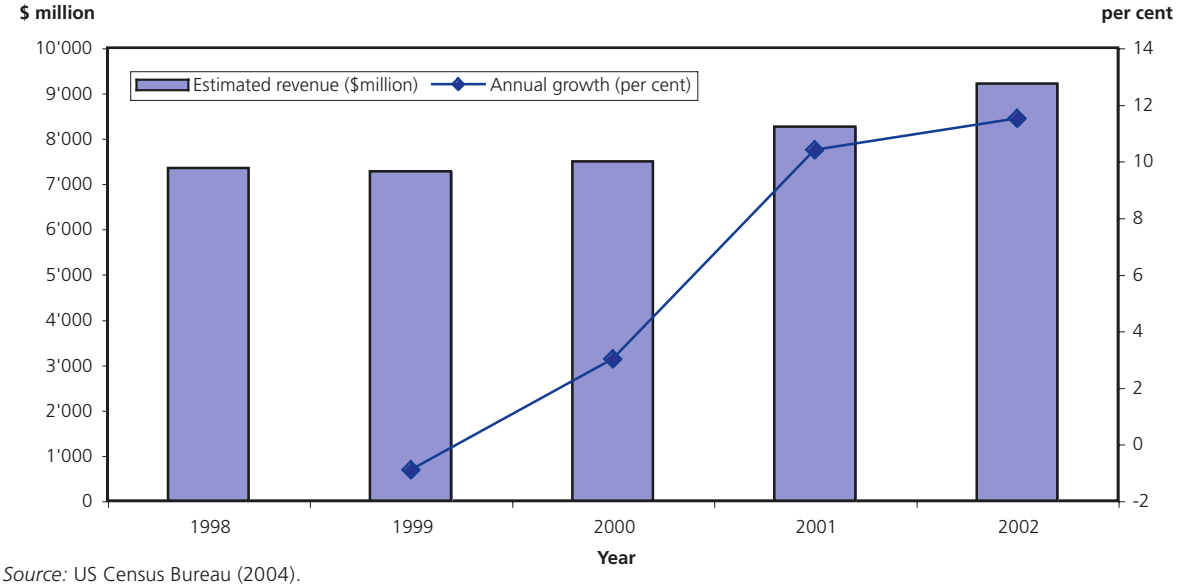
110 An on-site assessment is conducted before initial accreditation, during the first renewal year, and every two years thereafter. To the total cost, varying annual proficiency testing fees must be added, which are to be paid directly to an outside testing service provider. See NIST (2004).

111 Additional charges must be foreseen for travel, boarding and lodging of assessors and for possible extensions of the existing accredited scope per field of testing during NABL's annual surveillance activities. See NABL (2004).

112 Exchange rate information is for the year 2002. See Word Development Indicators (WDI) 2004 by the World Bank. Available at http://www.worldbank.org/data/wdi2004. The comparison of fees is quite crude and also strongly depends on how broadly product categories are defined for which a testing laboratory is accredited.

onto trucks, trains or vessels.[113] SGS is present in more than 130 countries world-wide, including many of the least-developed countries.[114] But in relation to "sensitive" products subject to strict regulatory requirements, exporting country governments may also take on the responsibility for inspection in order to prevent non-conforming commodities from being shipped. This seems to occur particularly in regard to exports of foodstuffs to countries with stringent SPS requirements: for instance, the Export Inspection Council of India (with almost 59 Export Inspection Agencies across the country) carries out inspections of black pepper for export to the United States, based on the standards and requirements of US Food and Drug Administration (FDA) and issues corresponding inspection certificates for use by US authorities.[115]

Chart 10
United States laboratory testing services, revenues



Source: US Census Bureau (2004).

There are both private and public certification bodies. On the private side, many profit-oriented testing laboratories take the additional step of becoming a certifier of products for a particular range of standards. For instance, MET Laboratories, Inc. is a widely-accredited third party laboratory that certifies regulatory requirements internationally in the areas of electrical, electronic and telecommunication products.[116] A number of private certification bodies also work on a not-for-profit basis, often developing and certifying to their own standards. One of the oldest such institutions is the Underwriters Laboratories (UL) with more than 600 published standards in the area of consumer safety, and the well-known "UL" mark that is licensed to be placed on certified products or their packaging. More recently, such bodies have emerged in the environmental field, such as Forest Stewardship Council (FSC) accredited certification bodies, which award the FSC logo on products from certified forest operations.[117] Public sector certification is concentrated in areas of public interest, especially in relation to health, safety and environmental regulations. For instance, the US Department of Agriculture offers certification of fresh fruit and vegetables against grading standards it has developed. Participation by producers is voluntary, albeit widespread for its practical advantages, including easier marketability of certified products. Grading is paid for by user fees and is voluntary except for commodities that are regulated for quality.[118]

[113] The SGS was founded in the 19th century as a grain shipment inspection house and today offers inspection, verification, testing and certification services. SGS has 39,000 employees and operates a network of about 1,000 offices and laboratories around the world. See http://www.sgs.com/about_sgs/in_brief.htm, accessed on 21 February 2005.

[114] See http://www.sgs.com/contact_us.htm, accessed on 21 February 2005.

[115] See http://www.eicindia.org/eic/inspection/blackpepper.pdf, accessed on 21 February 2005.

[116] For up-to-date information see the directory of 'Conformity Assessment Testing Laboratories' at the American Council of Independent Laboratories (ACIL). Website accessed on 3 February 2005 (http://www.acil.org).

[117] The FSC insists that it is not a certification body itself, but an accreditation forum for forest certifiers, as it does not itself certify forest operations or manufacturers and does not develop standards, but only provides a framework for standards development at the national or regional level through a multi-stakeholder consultative process.

[118] See the Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service at the US Department of Agriculture. Website accessed on 3 February 2005 (http://www.ams.usda.gov/fv/fvstand.htm).

Finally, the metrology infrastructure of a country usually comprises both public and private institutions. The most common model consists of a government-endorsed national measurement institute (NMI) and a network of accredited calibration laboratories (Gilmour, 1998). NMIs provide the primary metrology standards used in the economy – usually a prerogative of governments – but not every NMI needs to maintain standards for every possible measurement unit. A lot depends on the nature and diversity of the industrial structure. For high-technology sectors, the availability of essential reference standards is vital. For instance, the US semiconductor industry invests several billion dollars per year in metrology projects that also depend on access to a comprehensive system of traceable measurement standards provided by the National Institute of Standards and Technology (NIST) (Semerjian and Watters, 1998). But also countries, such as Slovenia, that are relatively "small" in terms of the number of measurements performed, need to ensure the availability of traceable reference standards at the national level, as accuracy is demanded for most industrial measurement tasks (Drnovsek and Topic, 1998). According to the Drnovsek and Topic study, Slovenia does not have a centralized NMI, such as NIST. Rather, it has a system of laboratories in place that transfer standards that are traceable to the international level to lower level laboratories, but do not realize SI units themselves. Apparently, the additional uncertainties introduced by such transfers are minor and do not, for the moment, warrant additional investment to achieve a higher level of metrological capabilities. However, in such cases, close collaboration with other metrological organizations becomes all the more important, and Slovenian metrology institutions have maintained close ties to NIST since their establishment, as well as to various European bodies and international organizations, such as the Bureau International des Poids et Mesures (BIPM) and the International Organization of Legal Metrology (OIML).

Many organizations at the international, regional and bilateral levels are active in providing technical assistance to developing countries in order to help them upgrade their conformity assessment infrastructure. As noted above, international and regional systems for conformity assessment, such as ILAC, APLAC, etc. have their own training programmes and facilitate the exchange of experiences and the conduct of bilateral training activities between members. Organizations with a wider mandate, such as the United Nations Industrial Development Organization (UNIDO) and the World Bank, are also active in the area of conformity assessment. UNIDO, in the context of assisting developing countries to enhance their industrial competitiveness, also helps to identify conformity assessment needs and possible donor funding. For instance, a $2.3 million project in Sri Lanka, largely financed by Norway, supported testing laboratories, metrology infrastructure and environmental management systems. UNIDO assisted in upgrading the equipment and skills of six testing laboratories (one rubber testing, one textile testing, two microbiology and two chemical laboratories) and in obtaining international accreditation. In addition, a new industrial metrology laboratory compliant with the relevant international standards was established. Assistance was also provided to the Sri Lanka Standards Institution (SLSI) to launch the national ISO 14000 certification scheme. Twenty auditors were trained and ten pilot companies guided to develop an ISO 14000 scheme. Since the completion of the project, all the requisite garment testing has been carried out in Sri Lanka and the test results accepted by EU counterparts (OECD/WTO, 2003).[119]

[119] A search for more examples on conformity assessment-related technical assistance, both national and regional, can be performed through the Doha Development Agenda Trade Capacity Building Database (TCBDB) established by the WTO jointly with the OECD. See http://tcbdb.wto.org/index.asp?lang=ENG. On the WTO website, there are also links to other databases on TBT-related technical assistance. See http://www.wto.org/english/tratop_e/tbt_e/tbt_tech_link_e.htm. Finally, the WTO jointly with the World Bank, the World Animal Health Organization (OIE), World Health Organization (WHO), and Food and Agriculture Organization (FAO) have established the Standards and Trade Development Facility (STDF) Database, which provides information on SPS-related technical assistance and capacity building projects (see the earlier discussion in Subsection IIC.1). See http://stdfdb.wto.org. The WTO manages or participates in a range of technical cooperation programmes in collaboration with other international agencies that may contain conformity assessment components, such as the Integrated Framework, in collaboration with ITC, IMF, World Bank, UNCTAD and UNDP and the Joint Integrated Technical Assistance Program (JITAP), which are specifically for Least-Developed Countries (LDCs). The WTO has also recently concluded a Memorandum of Understanding with UNIDO comprising a conformity assessment module that has already led to several concrete outcomes in some of the nine pilot countries. For instance, with the participation of interested importing countries, such as the EC and Switzerland, progress was made on the fulfilment of SPS requirements for Amazon nuts in Bolivia and potatoes in Egypt. For more on WTO technical assistance see http://www.wto.org/english/tratop_e/devel_e/teccop_e/tct_e.htm

In seeking assistance to build conformity assessment infrastructure with the ultimate goal of reaching international recognition, developing countries understandably focus on sectors of particular export interest to them. In addition, sectoral conformity assessment needs usually receive priority, where the requirements by importing nations are particularly inflexible and the hiring of foreign service providers is neither cost-effective nor practical. Many developed countries that for obvious reasons do not wish to lower their standards and the required level of conformity assurance, provide assistance on a bilateral basis to suppliers in the developing world. For instance, the Canadian Food Inspection Agency (CFIA), a governmental body tasked with enforcing food safety and nutritional quality standards and carrying out necessary inspections, collaborates with Chilean representatives on a "Food Safety Enhancement Program" with the objective of improving on-farm food safety in Chile and giving official recognition to its on-farm programmes.[120] Some of these projects can also have positive spill-over effects – after successful implementation, they lead to increased exports to third countries as well. For example, the EC had imposed restrictions on Kenyan exports of Nile perch. Subsequent up-grading efforts of fish-processing facilities (including the introduction of HACCP procedures) prompted the European Commission to recognize the controls in place as equivalent, and enabled Kenya fish exporters to gain access to new export markets in the United States, Japan and Australia (Jaffe and Henson, 2004).[121]

Conformity assessment requirements and goverment-to-government MRAs

While the provision of conformity assessment services at the national level poses problems, especially for developing countries, rigid prescriptions on conformity assessment by importing country governments[122] can be challenging even for countries with a well-developed conformity assessment infrastructure. Exporters may face extra costs due to: i) difficulties in obtaining information on conformity assessment requirements and admissible providers; ii) additional conformity assessment activities to those carried out domestically or a duplication of procedures; iii) procedures that are more costly to exporters than domestic producers owing, for instance, to higher transport and communication costs; and iv) administrative delays caused, for instance, by test reports and other documentation that may be refused, remitted for further clarification or, even when admissible, less familiar to importing country authorities.

Requirements in relation to any conformity assessment activity can affect trade in any of these four ways.[123] Common examples are the non-acceptance by the importing country of a supplier's declaration of conformity in a sector, where this is possible in the exporting country. For instance, supplier's declaration of conformity is commonly accepted in the motor vehicles and motor vehicle equipment sector in the United States, but not in many other countries. Conversely, it is used for electrical products in the European Communities, but has not been mentioned, for example, by the United States or Brazil in their submissions on product categories where supplier's declaration of conformity is permissible (WTO Secretariat, 2005b).

In relation to testing/inspection, importing countries may not accept foreign reports and require (re-) testing/ inspection by designated bodies. These may be bodies in the importing country that conduct the assessment upon arrival of the product or go to the exporting country, or selected bodies in the exporting country in which the importing country regulator has confidence. For instance, Mauritian inspection and test certificates regarding food safety requirements for canned tuna have, for some time, not been accepted in South Africa and so the canned tuna had to undergo re-testing and re-inspection there. Ultimately, an agreement was reached that the

120 See STDF Database at http://stdfdb.wto.org/trta_project.asp?ctry=25&prjcd=CAN-CFIA-33, accessed on 24 February 2005.

121 See also in the respective bulletins of the Centre for the Development of Industry (CDI), a joint Africa, Caribbean, Pacific (ACP)-European Union (EU) institution created in the framework of the Lome Convention; http://europa.eu.int/comm/development/body/publications/courier/courier171/en/91_en.pdf, accessed on 24 February 2005.

122 Of course, buyers can also make burdensome prescriptions on how and where specifications they require from the exporter are to be assessed. As noted earlier, this discussion concentrates on conformity assessment requirements by governments in relation to mandatory regulations.

123 The discussion here focuses on conformity assessment activities in the narrow sense, i.e. not on accreditation and metrology. The reason for this is that a lack of confidence in the metrological capabilities of foreign countries may translate into non-acceptance of test reports, certificates, etc. By the same token, refusal to accept conformity assessment results from bodies accredited by a foreign accreditation institution may be due to a lack of confidence in the competence of these bodies. If the workings of the accreditation system are at issue, these may be overcome in the course of MRA negotiations, which are discussed further below.

Department of Veterinary Services and the Mauritius Standards Bureau would seek accreditation by South Africa as an inspection body and testing laboratory respectively (ITC and Commonwealth Secretariat, 2003: 61). Especially in the case of food safety, it is often compulsory that tests and inspections be conducted before shipment in order to prevent the spread of diseases. This not only involves substantial costs for the exporter if inspectors have to be brought in from abroad, but may, in certain cases, prove impossible, at least in the short-term. The absence of inexpensive testing/inspection services can thus forestall the possibility to export, even though requirements could actually be fulfilled. For example, mangos from Jamaica, due to the possible presence of fruit flies, are only allowed into the United States if they underwent hot water treatment in special facilities not currently available in Jamaica (ITC and Commonwealth Secretariat, 2003: 58). Pre-shipment testing is sometimes also required in regard to technical requirements, such as maximum pesticide residue limits for fresh fruit and vegetables.

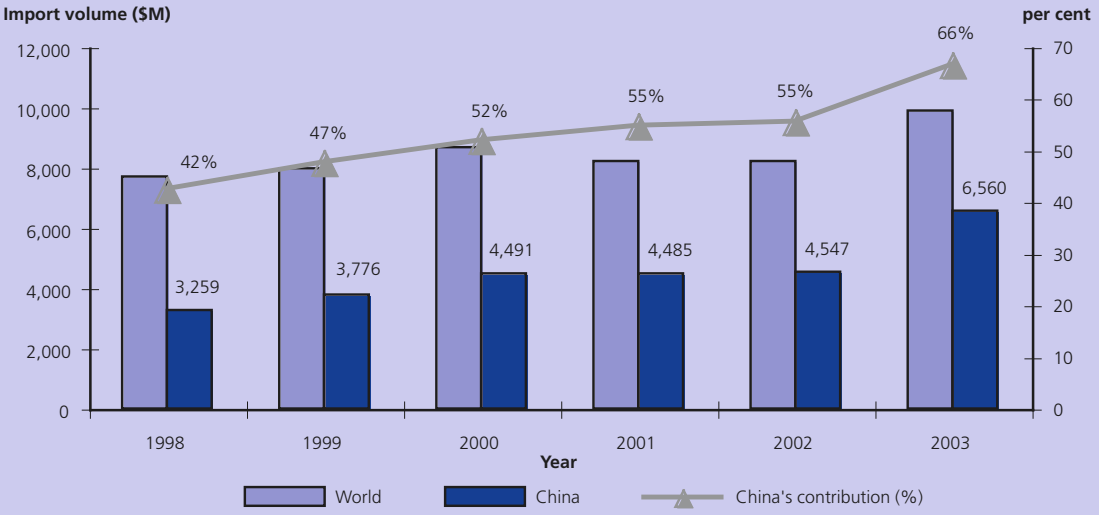
If certification is required, the mark of the exporting country may not be accepted by the importing country, which may insist on the use of its own certification programme before market clearance can be given. For instance, the "Global Approach", developed as a complement to the EC's New Approach to standardization (see earlier Box 9), describes various conformity assessment activities ("modules") and designates the bodies operating the individual procedures. For all modules, these so-called "notified" bodies have a special role in carrying out assessments, gathering documentation from suppliers or exerting oversight over other third-party institutions. Only notified bodies may ultimately give final approval in the regulated sectors, including the right to affix the "CE mark" on the product, without which products subject to "essential requirements" under the "New Approach" may not be put on the market. This means that, for many countries, depending on the required conformity assessment procedure, product samples have to be shipped to the EC for testing and certification by a notified body or expenses must be paid for EC inspectors to conduct necessary inspections or quality system registrations on-site. There is also the possibility that laboratories in the exporting country are subcontracted by EC certification bodies and forward their test data to the notified body for evaluation and final product approval (National Research Council, 1995). A brief description of the "Global Approach" and an example of how exporters deal with it is given in Box 11.

Box 11: The EC's "Global Approach to Testing and Certification" and the Toy Directive

As a complement to the EC's New Approach (see Box 9 above), the "Global Approach to Testing and Certification" and its "CE" mark ("Conformité Européenne", French for European Conformity) were created to ensure conformity of a product with applicable Directive(s). Directives contain "essential requirements" to be achieved in terms of product safety, etc., but do not stipulate the technical solutions for attaining them. Those are specified by European harmonized standards whose adoption is voluntary, but products meeting these standards automatically benefit from a presumption of conformity with the essential requirements set out in the Directive. Products covered by one of the Directives must bear the CE mark to gain marketing approval. The CE mark must be affixed on 21 types of products (as of January 2005) in all the 28 Member States of the European Economic Area (EEA). Manufacturers may choose among eight conformity assessment activities ("modules") to demonstrate compliance. Each Directive specifies which module or combination of modules is admissible, which may vary in relation to the perceived risks of the covered products. The modules are "Internal production control" (Module A), "EC type-examination" (Module B), "Unit verification" (Module G) and "Full quality assurance" (Module H), of which modules A, G and H refer to attestations that both the design of a product and produced units conform to the provisions of the applicable Directive. Module B refers to design only and may be combined with one of four modules referring to production: "Conformity to type" (Module C), "Production quality assurance" (Module D), "Product quality assurance" (Module E) and "Product verification" (Module F). Modules D, E and F, while normally used in combination with module B, may in special cases (for example, when dealing with certain products of very simple design and construction) be used on their own (European Commission, 1993a). The extent to which EC-accredited conformity assessment bodies, so-called "notified bodies" that have the exclusive right to award the CE mark, must be involved varies between the modules. The modular approach will be illustrated below in relation to toys.

The Toys Directive 88/378/EEC was introduced in 1988 as a means to protect the health and safety of children. It identifies essential requirements to protect children from general risks (protection against health hazards or physical injuries) and particular risks (physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity). In addition, the Directive requires the compilation of a Technical File which contains all the details regarding design, manufacture and operation of the toy as well as test data and results, on the basis of which conformity with the Toys Directive is assessed. There are currently eight European harmonized standards (the "EN 71" series) pertaining to the Toys Directive. Toy manufacturers are legally responsible for ensuring that their products meet the essential requirements set out by the Directive (depending on the type of toy, e.g. electric toys, other Directives may apply as well). While free to choose production techniques, the manufacturer benefits from the presumption of conformity in case the technical solutions specified by the European standards are followed. In that case, the manufacturer may pursue a self-declaration of conformity on the basis of the Technical File (Module A). If the European standards are not followed or followed only in part, a "notified body", accredited by the competent authorities of a Member State, verifies the Technical File, tests a sample of the toy and, if successful, issues an EC type-examination certificate to the manufacturer (Module B in combination with Module C). In both cases, the manufacturer must keep the Technical File available for future inspection. Once toys have been properly CE marked, they enjoy free circulation in the EEA. Member States are responsible for performing sample checks on toys being sold in their markets to verify their continuing conformity. Although "notified bodies" must reside in Europe, some have affiliates in third countries to assist local manufacturers. However, only in a few countries, with which the EC has concluded a Mutual Recognition Agreement (MRA), the actual certification can be carried out by local "designated bodies" in lieu of EC "notified bodies". This is the case, for instance, with the United States. Also, when the manufacturer is not a registered business in a EC Member State, a European Authorized Representative (EAR) must be designated who will keep the Technical File, serve as a contact person, provide information to competent authorities, and bear the legal responsibility. Alternatively, a distributor or an agent in Europe may act as the regulatory representative. The practical aspects of how to demonstrate conformity with the Toys Directive as a non-EC producer seems to be of increasing importance given the growth of toys imports from outside the EC, especially from China, in recent years.

European Union toy imports from Non-EU countries



Source: UN COMTRADE.

A frequent conformity assessment requirement relates to the certification of management systems. Commonly, registration with an accredited body according to international standards, such as the ISO 9000 series on quality management or the ISO 14000 series on environmental management systems, must be demonstrated. While such proof of good business practices is normally demanded by purchasers (and in the case of powerful buying associations may become *de facto* mandatory requirements), governments may also include prescriptions on management guidelines in some of their regulations. A case in point is the Hazard Analysis and Critical Control Points (HACCP) System, developed by the Codex Alimentarius Commission (see Box 12) and referenced widely in countries' food regulations. For instance, the European Communities have put in place Directive 93/43/EEC concerning the hygiene of foodstuffs, mandating the use of HACCP principles and encouraging the development of guidelines to good hygiene practice "where appropriate, having regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the Codex Alimentarius" (European Commission, 1993b: Article 5.2). HACCP principles are increasingly important for developing countries, given the importance of the food-processing sector in many of them and the extensive use of HACCP as part of food regulations, especially in the developed world. The implementation of HACCP can be challenging in terms of required skills and infrastructure, as process controls and third-party certification have to take place locally. This is confirmed by case studies conducted for Jamaica, Kenya, Malaysia, Mauritius, Namibia and Uganda by the ITC and Commonwealth Secretariat (2003), which cite compliance with SPS measures as being of primordial concern to their exporters.

Box 12: International food safety standards and HACCP

There are a number of international food safety standards, mainly developed by the FAO/WHO Codex Alimentarius Commission (CAC). Observance of international standards by developing countries, while costly initially, is often necessary to maintain market access and reduce the rate of rejection of unsafe or spoiled products in export markets.

In order to fulfil hygiene requirements, the CAC recommends a Hazard Analysis Critical Control Point (HACCP) approach. Developed in the 1960s by NASA, HACCP is a risk management tool at the firm level that relies on preventive measures, rather than a unique control of the final good, in order to eliminate contaminants at critical areas in the food production and distribution process. Under HACCP, food-related businesses are responsible for analysing how hazards may enter the product, establishing effective control points for those hazards and monitoring and updating the system to assure high levels of food safety. HACCP must be carried out in the exporting country. The burden of implementing HACCP lies with individual firms, but in order to achieve international recognition, the conformity assessment infrastructure must exist to deliver and renew certifications and perform periodic controls.

Already wide-spread in industrialized countries, HACCP has become increasingly popular in other countries. Adoption of and compliance with HACCP principles constitute a necessary, and sometimes even sufficient, condition for meeting international standards set by the CAC. Conformity with HACCP principles must then be certified by a domestic certification body and importing countries may require this body to meet the relevant ISO/IEC standards and/or the CAC "Guidelines for the Design, Operation, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems." CAC also developed guidelines on applying HACCP systems for small and less-developed businesses. An importing country may still insist on carrying out its own inspections in the exporting country. For example, when the EC imposed a ban on shrimp exports from Bangladesh for food safety reasons, EC inspectors evaluated on-site the measures put in place by local producers and authorities.

Source: International Food Policy Research Institute: www.ifpri.org; US FDA's Food Safety Gateway: http://www.foodsafety.gov/~fsg/fsghaccp.html; and World Health Organization: http://www.who.int/foodsafety/fs_management/haccp/, all websites accessed on 24 February 2005.

The systematic reporting of conformity assessment procedures as barriers to trade is extremely rare, especially for developing countries, where, at best, some anecdotal evidence is available. One example of a regular, systematic collation of foreign trade barriers that includes a section on conformity assessment for all reviewed trading partners, is the USTR's National Trade Estimate Report on Foreign Trade Barriers (NTE). From the 2004 NTE, it appears that mandatory certification in the importing country is relatively frequent, especially in the food sector. Similarly, a number of countries are listed that only accept test results from laboratories in their own country as supporting documentation for a mandatory certification (see Box 13 for selected examples). However, there are also cases where the report simply notes that, despite certain regulations, imports are, in practice, admitted into the country with little reference to actual conformity.[124]

Box 13: Selected examples of conformity assessment requirements faced by US exporters

The National Trade Estimate Report on Foreign Trade Barriers (NTE) is an annual survey that has been carried out for almost 20 years by the USTR to identify significant foreign barriers to US exports in main trading partner countries (USTR, 2004). In 2004, almost 60 export markets were covered. For each export market, the report contains a section on "standards, testing, labelling and certification (including unnecessarily restrictive application of sanitary and phytosanitary standards and environmental measures, and refusal to accept US manufacturers' self-certification of conformance to foreign product standards)". The examples given below are randomly selected to illustrate mandatory certification and testing requirements by the importing country, often, but not only relating to the food sector.

Certification

Many countries, both developed and developing, have restrictive certification requirements only in a few areas, notably in the biotechnology sector. Switzerland, for instance, grants marketing approval for bio-engineered foods and additives exclusively through certification by the Federal Food Safety Office.

The Thai government requires a compulsory certification by the Thailand Industrial Standards Institute (TISI) of 60 products in ten sectors, including: agriculture, construction materials, consumer goods, electrical appliances and accessories, PVC pipe, medical equipment, LPG gas containers, surface coatings and vehicles.

India has identified 159 specific commodities (including food preservatives, milk powder, condensed milk, infant milk foods, colour dyes, steel, cement, electrical appliances and dry cell batteries) that the Bureau of Indian Standards (BIS) must certify before the products are allowed to enter the country. To be certified, exporters/manufacturers must either establish a presence in India or name a local Indian representative to accept responsibility, pay an annual fee as well as a percentage of the invoice value of shipments to India, and subject all certified exports to inspection.

Testing

In Indonesia, all imported food products must be tested by the Agency for Drug and Food Control (BPOM). Fees for such testing range from Rp 50,000 ($6.00) to Rp 2.5 million ($300) per item, and between Rp 1 million ($120) to Rp 10 million ($1200) per product.

El Salvador requires importers to deliver samples of all foods for laboratory testing to the Ministry of Public Health, which upon approval issues the product registration numbers that allow the imported goods to be sold at retail outlets. In the past, some processed foods that were approved in the United

[124] This is the case, for instance, for Cameroon. See USTR (2004): 35.

States were reported to have been rejected after analysis in El Salvador, thereby barring their sale. The United States and the Salvadorian Ministry of Public Health initiated discussions on this issue in 2002. Apparently, an agreement has not been reached yet to allow entry of US-approved products, and this issue forms part of the CAFTA negotiations on acceptance of testing results.

In the manufacturing sector, it is often pharmaceuticals and chemicals that are subject to double testing in the importing country. The Korean government, for instance, requires that each shipment of a drug imported into the Republic of Korea for commercial purposes be tested once registered.

For Argentina, the report notes conformity assessment procedures, including re-testing, for US exports of low voltage electrical products (household appliances, electronics products and electrical materials), toys, covers for dangerous products, gas products, construction steel, personal protective equipment and elevators.

In order to address problems faced by exporters in an importing country with rigid prescriptions on the conformity assessment institutions, and activities or procedures that may be used, governments often engage in the negotiation of MRAs. Divergent ideas about which conformity assessment procedures to conduct, which bodies to consider competent, and the multitude of systems at the national level often make the conclusion of MRAs more time-consuming and costly than originally foreseen. For instance, in the US-EC MRA, differences in accreditation concepts needed to be addressed. The EC had difficulty in accepting US accreditation programmes that were largely private, decentralized and of a complex nature, as they had arisen in a rather uncoordinated fashion through case-by-case responses to specific industry demands. Conversely, the EC required some form of government involvement in accreditation, which prompted the United States to introduce the concept of governmental recognition of private accreditors. It developed the National Voluntary Conformity Assessment Systems Evaluation (NVCASE), administered by NIST, to provide for government recognition of its multiple private accreditation institutions and create accreditation programmes in sectors where there were none.

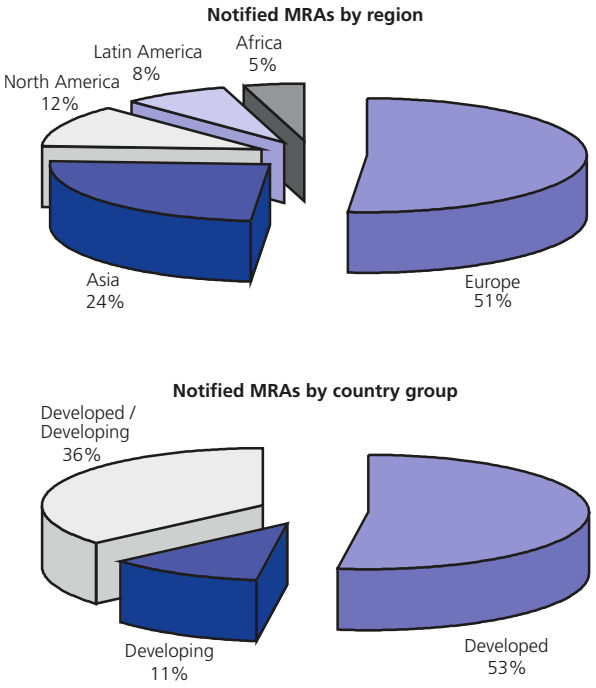
In contrast, the United States objected to the fact that there was no mechanism by which a non-European organization could become a "notified" body exclusively entitled to perform certain testing and certification operations under the EC's "Global Approach to Testing and Certification". The MRA ultimately comprised six sectoral annexes containing detailed provisions on the degree of acceptance of conformity assessment results. For instance, for electrical safety equipment, the test reports of US bodies are to be accepted by EC authorities "in the same way that reports from European Community notified bodies are accepted", or for electromagnetic compatibility devices, the test reports as well as certificates "shall be recognized by the Regulatory Authorities of the other Party without any further conformity assessment of the products" (US Mission to the European Union, 1998: pp. 21 and 36). The difficulties involved in the US-EC MRA negotiations are also underlined by the fact that six sectoral annexes with differing levels of commitments had to be devised (telecommunication equipment, electromagnetic compatibility (EMC), electrical safety, recreational craft, pharmaceutical good manufacturing practices (GMPs) and medical devices). A general acceptance of test results, inspections and product/systems certifications for all 11 sectors that had originally been under negotiation – an objective that, at least, the European side had stated repeatedly – turned out not to be possible (Wilson, 2000). Wilson also observed that differences in assurance needs in certain sectors were simply too wide, in particular since the "European system does not rely on firms' self-declaration of conformity as widely as the US system does" (Wilson, 2000: p. 3).

In sum, the greater the difference between existing systems for conformity assessment in two countries, the greater the difficulties in negotiating and maintaining MRAs. Differences of view in regard to the classes of products subject to third-party assessment or government control, as well as on the technical aspects of what constitute appropriate procedures, mistrust in the competence of conformity assessment bodies, and different accreditation requirements and procedures all increase the time and resources needed to achieve

mutual recognition. This is why, in general, MRAs seem more likely between countries at higher and similar levels of development. By and large, this reality seems to be confirmed by the number of MRAs notified to the WTO under TBT Article 10.7 (see Chart 11). The low number of MRAs with African participation is particularly noteworthy, as well as the fact that more than half of all notified agreements involve developed countries only.

Of course, the levels of ambition also vary amongst different government-to-government MRAs. Any MRA will clearly specify the product sectors to which it applies, which may be only a few. There is also a difference as to whether merely raw test/inspection data by accredited foreign bodies are admitted as inputs into domestic compliance decisions or whether recognized foreign bodies are entitled to give de facto final marketing approval in the importing country. The former appears to be the case, for instance, for medical devices in the context of the US-EC MRA, where US conformity assessment bodies listed in the annex only qualify to provide reports on quality systems to an EC notified body for its endorsement. While endorsement is meant to be the norm, the notified body may request a re-inspection or, ultimately, perform the quality systems evaluation itself (US Mission to the European Union, 1998: pp. 90-91).

Chart 11
Notified MRAs by region and country group



Source: Based on WTO Secretariat (2005c).

It is difficult to draw any general conclusions on the level of ambition from the information contained in the database on MRA notifications under TBT Article 10.7. Sometimes the notifications do not specify the products covered, and if they do, the product range is usually quite narrow. The Japan-US MRA, for instance, is confined to the mutual acceptance of each party's grading system of organic agricultural products and processed organic foods. A number of agreements refer to the acceptance of test reports only, such as the MRA between Chinese Taipei and Canada to accept test reports for specified information technology equipment. Some MRAs specifically include the acceptance of each other's certificates, for example the MRA between Australia and Thailand on road vehicles, equipment and parts. Wilson (1995) and Stephenson (1997) caution that the acceptance of certifications granted by other countries is in practice quite rare. For the members of the Asia Pacific Economic Co-operation (APEC), they find that MRAs on certification issues are often not only limited to specific sectors, but also subject to special conditions.

3. CONCLUSIONS

While information on standardization at the international level is fairly comprehensive and easily accessible, for most countries it is very difficult to obtain a complete picture of standardization infrastructure at the national level on the basis of available information. The emerging parts of the iceberg are ISO plus a few other international standardization bodies and the member bodies of ISO. Information on whatever takes place outside of this system is scattered, incomplete and heterogeneous.

The overview suggests that the standards development process organized by national, regional and international standards institutions is progressively evolving. The role of international bodies has gained prominence. The national standardization infrastructures of most industrialized countries are now integrated into the network of international standardization. In Europe, for instance, adoption of European standards

is mandatory for national member bodies and European standards organizations transpose the international standards into European standards. Many developing countries are also participating in the system. Close to 40 per cent of Malaysian standards are "aligned" with international standards and this proportion is rapidly growing as more standards are revised and new standards developed are increasingly based on international standards.

A considerable number of low-income and transition countries have not, however, followed the trend. Their national institutions are not part of the international network. ISO, for instance, has only three member bodies from LDCs and more than half of LDCs have no formal contact with ISO. Contrary to expectations, countries with scarce resources and limited capacity do not necessarily have many adopted international standards. In fact, resource constraints seem to restrict poor countries' integration into the international standardization system as much if not more than their own standardization activities.

The development process for voluntary, consensus based standards, and in particular the procedures used by ISO and many of its member bodies, are strictly regulated by the WTO and ISO codes of good practice. The process consists of several distinct but closely related activities. It is fairly open and transparent but producers who have clear priorities and are usually better organized than consumers typically play the leading role. In some industrial countries, governments actively promote the participation of consumers by funding consumer organizations. Institutions which compete with less formal private standardization initiatives are concerned that the whole process may be too slow.

In principle, the trend is towards separating standardization activities from regulatory activities, with the former left to the private sector and the latter with the public sector. The separation between public and private standard setting, however, is not always clear cut. The organization of the process of standardization varies widely across countries. In general, regulations concerning safety, health and the environment are issued by governments. Often, however, the specific measures that satisfy the objectives of government regulations are spelled out in technical standards developed by private organizations. In European countries, for instance, the government refers to privately developed standards in regulations. Standards institutions in poorer countries are generally in the public sector, with little or no participation of the private sector. In a small number of countries, mainly in Africa, the CIS and the Middle-East, the share of national standards with a mandatory status exceeded 50 per cent of the total number of standards published at the end of 2002.

Improving participation of developing countries in international standardization is crucial. This has been recognized for several decades and, as discussed below, numerous initiatives have been undertaken to improve the situation. Recent evidence, however, suggests that these initiatives have not achieved much improvement yet. And progress may be slow as the main difficulty for developing countries seems to be the lack of expertise needed for participation in the work at the technical level on the formulation of standards and the limited support from the private sector.

Conformity assessment is an everyday reality in commercial transactions. Purchasers and regulators want to ensure that the requirements and standards they impose on suppliers are fulfilled. Assessment procedures carried out by suppliers themselves or third-parties add to transactions costs. Sometimes these costs can be larger for foreign suppliers than for domestic ones. This may be the case, for instance, if a certification of compliance with a product regulation can only be given by domestic bodies in the importing country. If the exporter is required to comply with the same regulation in its home country, a double examination puts it at a disadvantage. By the same token, it is understandable that regulators wish to rely on conformity assessment results from sources in whose competence and integrity they have full confidence.

A lot of international cooperation is taking place to establish confidence in the work of conformity assessment bodies in other countries. An efficient way forward seems to be the conclusion of mutual recognition agreements (MRAs) between accreditation bodies such that the results of any laboratory or other conformity assessment body accredited by one of the parties are accepted in any other country. In order for this happen, it is important that common standards on best practices are adhered to, giving other parties confidence in the work of their partners. However, while such MRAs may, in practice, help purchasers to gain trust in the results

of foreign bodies, it is not certain to what extent they are relied upon by governments in regulated sectors. A range of government-to-government MRAs, which are often bilateral or plurilateral with only a few parties at similar and higher levels of development, show that commitments to mutual acceptance of conformity assessment results in sectors involving health, safety and environmental concerns tend to be quite limited.

In developing countries, the provision of conformity assessment services is often inadequate or costly. Given that many activities, such as testing, inspection and certification can be profit-making enterprises, the question arises what factors impede their provision by the private sector and to what extent governments need to step in. Regional provision, especially of accreditation services, has proven a viable way forward for smaller and poorer countries. Considerable technical assistance is provided from a variety of sources in the endeavour to build the necessary conformity assessment infrastructure. Priority is usually given to conformity assessment needs of sectors of particular export interest in developing countries facing stringent conformity assessment requirements in major export markets.

A major problem in drawing a conclusion on where efforts in the area of conformity assessment and trade should be concentrated is the absence of empirical studies. For instance, it would be important to know how the costs of negotiating an MRA compare to the savings made in terms of reduced testing needs. While there is an almost confusing multitude of publications describing institutional arrangements and conformity assessment concepts at length, often in very general terms and without concrete examples, there is a shortage of comparative analyses of conformity assessment practices across sectors or countries. There seems to be a clear need for all organizations involved in the field of conformity assessment to shift their research focus towards more applied, quantitative analysis of existing experiences and a systematic collection of cost data.

APPENDIX TABLES

Appendix Table 1
World Standard Services Network list of international standardizing bodies

- **BIPM** – Bureau international des poids et mesures
  Scope: Units, standards and methods of measurement of physical quantities.
- **BISFA** – International Bureau for the Standardization of Man-made Fibres
  Scope: Specification and testing of man-made fibres.
- **CCSDS** – Consultative Committee for Space Data Systems
  Scope: Space-related information technologies, data handling techniques.
- **CIB** – International Council for Research and Innovation in Building and Construction
  Scope: Pre-standardization work in the field of building and construction.
- **CIE** – International Commission on Illumination
  Scope: Metrology in the fields of light, lighting and colour; science, technology and art of light, lighting and colour.
- **CIMAC** – International Council on Combustion engines
  Scope: Acceptance tests for combustion engines; noise; pollution.
- **CODEX** – Codex Alimentarius Commission
  Scope: Specification, sampling and analysis of food products; food additives; food hygiene; pesticide residues; contaminants; labelling; essential composition; nutritional aspects; veterinary drug residues; food import/export inspection and certification systems.
- **CORESTA** – Cooperation Centre for Scientific Research Relative to Tobacco
  Scope: Analysis and testing of tobacco and tobacco products.
- **FDI** – World Dental Federation
  Scope: Dental materials; dental instruments and equipment; working environment of the dentist.
- **FIATA** – International Federation of Freight Forwarders Associations
  Scope: Freight forwarding services.
- **IAEA** – International Atomic Energy Agency
  Scope: Nuclear energy; nuclear and radiation safety; radioisotopes; documentation.
- **IATA** – International Air Transport Association
  Scope: Procedures for airport and passenger services. Procedures for cargo services, including shipping of live animals and dangerous goods. Minimum standards for IATA accreditation of cargo and passenger agents and their modus operandi.
- **ICAO** – International Civil Aviation Organization
  Scope: Air transport; air navigation; aviation safety; airports design; airworthiness; aircraft noise; international law, etc.
- **ICC** – International Association for Cereal Science and Technology
  Scope: Testing and analysis of cereals and cereal products.
- **ICDO** – International Civil Defence Organisation
  Scope: Disaster management and prevention.
- **ICID** – International Commission on Irrigation and Drainage
  Scope: Irrigation and drainage; terminology.
- **ICRP** – International Commission on Radiological Protection
  Scope: Radiation hazards and radiation protection.
- **ICRU** – International Commission on Radiation Units and Measurements
  Scope: Radiation units and measurements; radiation dosimetry.
- **ICUMSA** – International Commission for Uniform Methods of Sugars Analysis
  Scope: Methods of sugar analysis.
- **IDF** – International Dairy Federation
  Scope: Milk and milk products (composition, sampling and analyses); milk farm and factory equipment; disinfectants.
- **IEC** – International Electrotechnical Commission
  Scope: Electrical and electronic engineering.

- **IETF** – Internet Engineering Task Force
  Scope: Internet architecture and operation.
- **IFLA** – International Federation of Library Associations and Institutions
  Scope: Bibliographic control and other aspects of library matters.
- **IFOAM** – International Federation of Organic Agriculture Movements
  Scope: Organic agriculture and processing.
- **IGU** – International Gas Union
  Scope: Gas transmission distribution and utilization safety; use of SI units in gas industry.
- **IIR** – International Institute of Refrigeration
  Scope: Tests of thermal performance of insulated vehicles; tests of insulating materials; refrigerated storage and transport of perishable foodstuffs; food freezing; refrigerating equipment; terminology.
- **IIW** – International Institute of Welding
  Scope: Welding and allied processes.
- **ILO** – International Labour Office
  Scope: Working conditions and environment; occupational safety and health; equality of treatment between men and women; non-discrimination; rights of tribal and indigenous peoples; employment.
- **IMO** – International Maritime Organization
  Scope: Maritime safety; prevention of pollution from ships; facilitation of international maritime traffic.
- **IOOC** – International Olive Oil Council
  Scope: Table olives; olive oil; olive-pomace oils.
- **ISO** – International Organization for Standardization
  Scope: All fields except electrical and electronic engineering.
- **ISTA** – International Seed Testing Association
  Scope: Seed testing.
- **ITU** – International Telecommunication Union
  Scope: ITU-T: All aspects of telecommunication equipment, systems, networks and voice and non-voice services. All related technical, operating and administrative areas. ITU-R: Radiocommunications.
- **IULTCS** – International Union of Leather Technologists and Chemists Societies
  Scope: Analysis and testing of leather.
- **IUPAC** – International Union of Pure and Applied Chemistry
  Scope: Nomenclature, terminology, symbols, quantities and units in chemistry.
- **IWTO** – International Wool Textile Organization
  Scope: Testing of wool textiles.
- **OIE** – International Office of Epizootics
  Scope: Standards for the international trade in animals and animal products, diagnostic techniques, reference reagents, vaccines and procedures for international reporting of transmissible animal diseases.
- **OIML** – International Organization of Legal Metrology
  Scope: Measuring methods and units; measuring devices and instruments; verification and control of measuring devices (from a legal point of view).
- **OIV** – International Vine and Wine Office
  Scope: Methods of wine analysis; oenology; labelling.
- **OTIF** – Intergovernmental Organisation for International Carriage by Rail
  Scope: International carriage of dangerous goods by rail.
- **RILEM** – International Union of Laboratories and Experts in Construction Materials, Systems and Structures
  Scope: Nomenclature and testing of building materials and structures.
- **UIC** – International Union of Railways
  Scope: International railway traffic.
- **UN/CEFACT** – Centre for the Facilitation of Procedures and Practices for Administration, Commerce and Transport
  Scope: Trade facilitation and electronic business.
- **UNESCO** – United Nations Educational, Scientific and Cultural Organization
  Scope: Scientific and technological information and documentation, libraries and archives.

- **UPU** – Universal Postal Union
  Scope: Compatible postal operations.
- **WCO** – World Customs Organization
  Scope: Classification; customs valuation; customs procedures; customs applications of computers; harmonization of Rules of Origin.
- **WHO** – World Health Organisation
  Scope: All matters directly or indirectly related to health, including biological and pharmaceutical and similar products and substances, food additives, pesticides, pesticide residues in food, food safety, air and water quality, diagnostic procedures, terminology, nomenclature and classification.
- **WIPO** – World Intellectual Property Organisation
  Scope: Patents; trademarks; industrial designs; appellations of origin; copyright; neighbouring rights; classification systems.
- **WMO** – World Meteorological Organization
  Scope: Meteorological and hydrological observations; agricultural, aeronautical and marine meteorology; data processing and telecommunications.

Source: http://www.wssn.net/WSSN/print/listings/links_international.html

Appendix Table 2
ISO Member Bodies: resources and standardization activities, 2002

Country	ISO status	Staff directly employed by ISO member	Annual budget 2002 (Thousands of Swiss francs)	Number of organizations to which standards development work is delegated	Government subsidy in % of total revenue	Total number of standards published at 31/12/2002	Voluntary standards in % of total number of standards	Number of international standards adopted as national standards at 31/12/2002
Africa								
Algeria	Member	75	602	130	71	6177	98	5360
Angola	Correspondent	...	341	...	100	...	...	...
Benin	Subscriber	10	300	120	60	4	50	...
Botswana	Member	66	4503	...	77	181	93	64
Burundi	Subscriber		44	...	100	...	...	...
Cameroon	Correspondent	7	90	...	80	204	95	170
Congo, Democratic Rep. of	Correspondent	141	7375	...		2	100	...
Côte d'Ivoire	Member	23	483	...	12	560	60	186
Egypt	Member	825	7269	...	100	4183	91	959
Eritrea	Subscriber	34	495	17	...	334	0	...
Ethiopia	Member	328		...		389	0	...
Ghana	Member	367	2744	...	73	226	0	370
Kenya	Member	657		...	56	3021	35	1243
Lesotho	Subscriber	11	100	...	100	...	...	...
Libya	Member	40		...	90	479	0	...
Madagascar	Correspondent	...	175	...	53	67	90	...
Malawi (1999)	Correspondent	145	2100	...	52	450	70	155
Mali	Subscriber	45	250	...	100		75	
Mauritius	Member	71	1600	...	63	149	92	38
Morocco	Member	25	600	8	100	3707	98	1221
Mozambique	Correspondent	15	97	...	82	16	94	5
Namibia	Correspondent	6		...	100	...	...	...
Niger	Subscriber	7	48953	...	100	...	...	...
Nigeria	Member	164	331	10	77	578	96	9
Rwanda	Correspondent	...	639	...	100	6	50	6
Senegal	...	...	...	...	...	...	...	...
Seychelles	Correspondent	...	1500	...	73	67	88	8
South Africa	Member	1032	45000	...	26	4966	99	1430
Sudan	Correspondent	720	3500	4		628	0	1100
Swaziland	Correspondent	3	...	...	100	...	...	...

Appendix Table 2
ISO Member Bodies: resources and standardization activities, 2002 (cont'd)

Country	ISO status	Staff directly employed by ISO member	Annual budget 2002 (Thousands of Swiss francs)	Number of organizations to which standards development work is delegated	Government subsidy in % of total revenue	Total number of standards published at 31/12/2002	Voluntary standards in % of total number of standards	Number of international standards adopted as national standards at 31/12/2002
Tanzania	Member	123	1884	...	39	738	68	328
Tunisia	Member	104	2154	...		5401	85	4320
Uganda	Correspondent	85	1696	...	75	467	70	121
Zambia	Correspondent	...	216	1	85	400	97	12
Zimbabwe	Member	72	2565	...	50	1195	96	195
Asia								
Australia	Member	478	68573	2	2	6664	75	1877
Bangladesh	Member	478	2347	...	11	1729	92	115
Brunei Darussalam	Correspondent	...	...	...	100	25	100	14
Cambodia	Subscriber	...	...	25	100	10	80	3
China	Member	60	16580	...	100	20206	86	8931
Chinese Taipei	...	...	...	...	...	...	...	...
Fiji	Subscriber	5	54	...	100	17	65	4
Hong Kong, China	Correspondent	214	26700	...	100	...	...	...
India	Member	1996	23844	...	...	17764	99	1070
Indonesia	Member	123	2077	14	100	5868	97	1100
Japan	Member	108	26500	588	100	9009	100	...
Korea, Dem. People's Rep. of	Member	187	100	204	100	11100	0	752
Korea, Rep. of	Member	244	32732	...	100	15176	100	7054
Macao, China	Correspondent	60	5000	...	92	10	0	...
Malaysia	Member	40	2500	1	100	3702	98	1064
Mongolia	Member		587	102		3776	21	1057
Nepal	Correspondent	104	387	...	100	654	99	30
New Zealand	Member	48	5800	2	...	2371	95	911
Pakistan (1999)	Member	152	630	2000	...	4602	99	1902
Papua New Guinea	Correspondent	13	286	...	23	1400	86	1400
Philippines	Member	87	679	25	100	1941	95	1167
Singapore	Member	544	28910	...	82	824	76	273
Sri Lanka	Member	304	1774	...	21	1627	98	448
Thailand	Member	485	11997	...	100	2347	97	272
Viet Nam	Member	964		...	60	5370	94	1400

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Central and Eastern Europe, Baltic States, CIS								
Albania	Correspondent	25	250	70	95	7038	100	3479
Armenia (1999)	Member	420	1055	20	4	272	70	8
Azerbaijan	Member		1440	8	70	567	10	6
Belarus	Member	46	1000	39	100	20593	50	2319
Bulgaria	Member	1174	300	75	43	17194	100	929
Czech Rep.	Member	176	6790	...	36	26082	100	5379
Estonia	Correspondent	20	621	22	51	10266	100	1978
Georgia	...	...	...	...	...	...	...	...
Hungary	Member	120	6715	...	26	22283	100	1488
Kazakhstan	Member	28	3867	48	100	400	0	22
Kyrgyzstan	Correspondent	136	296	3	100	515	50	6000
Latvia	Correspondent	29	466	40	70	10739	100	4207
Lithuania	Correspondent	58	1415	745	80	11743	100	708
Moldova, Rep. of	Correspondent	185	299	...	100	574		110
Poland	Member	294	8738	8	75	25613	98	6843
Romania	Member	86	885	...		22710	100	5718
Russia	Member	190	9440	28	82	22219	60	560
Slovakia	Member	108	2948	420	57	26295	100	2031
Turkmenistan (1999)	Correspondent	22	4010	8	2	600	0	12
Ukraine	Member	132	1242	1	100	23585	75	3010
Uzbekistan (1999)	Member	925	...	...	15	2679	0	...
Latin America								
Antigua and Barbuda	Subscriber	...	139	...	90	1	0	...
Argentina	Member	170	6261	...		7710	91	101
Barbados	Member	29	1200	...	90	200	78	70
Bolivia	Correspondent	43	1200	11		1300	65	200
Brazil	Member	73	5771	...	17	9271	100	340
Chile	Member	50	1738	...	11	2583	60	651
Colombia	Member	170	7200	5	2	5000	100	1370
Costa Rica	Member	16	885	...	2	344	100	80
Cuba	Member	1068	6	...	60	4278	94	2353
Dominica	Subscriber	6	250	...	100	...	...	...

Appendix Table 2
ISO Member Bodies: resources and standardization activities, 2002 (cont'd)

Country	ISO status	Staff directly employed by ISO member	Annual budget 2002 (Thousands of Swiss francs)	Number of organizations to which standards development work is delegated	Government subsidy in % of total revenue	Total number of standards published at 31/12/2002	Voluntary standards in % of total number of standards	Number of international standards adopted as national standards at 31/12/2002
Dominican Rep. (1999)	Subscriber	60	503	...	62	523	77	24
Ecuador	Member	87	1399	...	4	2318	75	27
El Salvador	Correspondent		375	2		904	92	835
Grenada	Subscriber	9	267	...	65	117	89	21
Guatemala	Correspondent	7	88	5	100	706	9	16
Guyana (1999)	Subscriber	42	28	...	98	172	...	94
Honduras	Subscriber	...	...	...	...	12	80	12
Jamaica	Member	149	8412	...	20	343	56	45
Mexico	Member	104		7	100	5570	85	...
Nicaragua	Correspondent	...	204	...	100	...	10	...
Panama	Member	8	167	...	100	522	85	10
Paraguay	Correspondent	173	2532	...	70	529	99	17
Peru	Correspondent	273	15270	...	11	3800	99	202
Saint Lucia	Correspondent	11	333	25	100	57	63	10
Saint Vincent and the Grenadines		...	...	...	...	...	...	...
Trinidad and Tobago	Member	200	4225	...	39	505	70	255
Uruguay	Member	35	1500	...	...	1561	91	254
Venezuela	Member	67	2435	17	...	3804	90	454
Middle East								
Bahrain	Member	21	977	2	95	1685	75	245
Iran	Member	1322	33551	1	29	6400	93	4800
Iraq	Member			...	...	...	...	...
Israel	Member	730	59700	...	3	2475	76	906
Jordan	Member	165	6502	...	100	1607	65	326
Kuwait	Member		2250	5	88	1247	72	62
Lebanon	Correspondent	6	1000	2	100	655	85	86
Oman	Member	70	...	4	100	1780	94	137
Palestine	Subscriber	91	730	...	100	621	43	55
Qatar	Correspondent	123	6112	2	100	1071	79	222
Saudi Arabia	Member	522	27000	...	89	2136	11	268
Syrian Arab Rep.	Member	110	300	...	100	2250	18	
United Arab Emirates	Member	18	3750	10	100	1062	75	...
Yemen	Correspondent	134	965	...	85	...	...	...

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North America								
Canada	Member	88	11000	4	56	2143	100	1053
USA	Member	77	24426	194	3	...	100	836
Western Europe								
Austria	Member	120	18000	1	11	14106	74	2219
Belgium	Member	42	6570	2	29	17170	99	11000
Bosnia and Herzegovina	Member	23	423	194	60	13626	40	2158
Croatia	Member	149	4925		49	6057	100	2699
Cyprus	Member	13	1087	3	85	10000	97	10000
Denmark	Member	176	27235		29	17496	95	
Finland	Member	60	9000	15	28	16532	99	2698
France	Member	630	119500	28	...	26544	99	9911
Germany	Member	727	140000	15	11	27179	100	8860
Greece	Member	89	7140	...	36	12384	...	1897
Iceland	Member	9	1296	1	63	13106	100	4754
Ireland	Member	167	...	...	24	272	100	12619
Italy	Member	120	21905	14	24	15561	95	1197
Luxembourg	Member	7	1106	52	100	14197	100	5560
Macedonia, the former Yugoslav Rep. of	Member		70		100	11657	100	2
Malta	Member	25	1000	8	90	12000	100	113
Netherlands	Member	220	32200	...	1	22053	100	10092
Norway	Member	14	2760	4	33	11775	89	2650
Portugal	Member	11	12710	48	19	5241	100	732
Serbia and Montenegro	Member	105	1133	...	100	13933	39	1533
Slovenia	Member	31	2828	...	75	15055	100	1776
Spain	Member	430	66797	...	5	19735	80	3611
Sweden	Member	160	31400	...	10	21800	100	4675
Switzerland	Member	30	8000	5		13950	100	3500
Turkey	Member	1408	76252	...		26572	100	6550
United Kingdom	Member	5175	500626	38	1	22589	100	10145

Source: ISO Members Directory 2003.