Leveraging the Impact of Business Environment Reform: The Contribution of Quality Infrastructure

Lessons from Practice

Working Paper

By Martin Kellermann and Daniel Paul Keller

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List of Acronyms

ACCSQ	-	ASEAN Consultative Committee for Standards and Quality
AFRAC	-	African Regional Accreditation Cooperation
AFRIMETS	-	Intra-African Metrology System
AIDMO	-	Arab Industrial Development and Mining Organisation
APLAC	-	Asia Pacific Laboratory Accreditation Cooperation
AMN	-	MERCOSUR Standardisation Association
APMP	-	Asia Pacific Metrology Programme
ARSO	-	African Standards Organisation
ASEAN	-	Association of Southeast Asian Nations
BEWG	-	Business Environment Working Group (under DCED)
BIPM	-	Bureau International des Poids et Mesures
BMZ	-	Bundesministerium für Wirtschaftliche Zusammenarbeit und Entwicklung
BSN	-	Badan Standardisasi Nasional (Indonesia)
CAB	-	Conformity Assessment Body
CAC	-	Codex Alimentarius Committee
CARICOM	-	Caribbean Community
CROSQ		CARICOM Regional Organisation for Standards and Quality
CEN	-	European Committee for Standardisation
CENELEC	-	European Committee for Electrotechnical Standardisation
CIPM	-	Comité International de Poids et Mesures
COOMET	-	Euro-Asian Cooperation of National Metrology Institutes
CYS	-	Cyprus Organisation for the Promotion of Quality
DCED	-	Donor Committee for Enterprise Development
DI	-	Designated (Metrology) Institute
DSM	-	Department of Standards Malaysia
EA	-	European Cooperation for Accreditation
EAC	-	East African Community
EAEC	-	Eurasian Economic Community
EASC	-	East Africa Standards Committee
ECOWAS		Economic Community of West African States
EU	-	European Union
EURAMET	-	European Association of National Metrology Institutes
FAO	-	Food and Agriculture Organisation (United Nations)
IAAC	-	Inter-American Accreditation Cooperation
IAF	-	International Accreditation Forum
IEC	-	International Electrotechnical Commission
IFC	-	International Finance Corporation
ILAC	-	International Laboratory Accreditation Cooperation
IPPC	-	International Plant Protection Convention
ISO	-	International Organisation for Standardisation
ITC	-	International Trade Centre
NAB	-	National Accreditation Body
NC	-	National Committee of the IEC
NMI	-	National Metrology Institute
NORAD	-	Norwegian Development Agency

NSB	-	National Standards Body
OECD	-	Organisation for Economic Co-operation and Development
OIE	-	World Organisation for Animal Health
OIML	-	Organisation Internationale de Métrologie Légale
PAC	-	Pacific Accreditation Cooperation
PASC	-	Pacific Area Standards Conference
PTB	-	Physikalisch-Technische Bundesanstalt
QI	-	Quality Infrastructure
ROM	-	Result-Oriented Monitoring
RTA	-	Regional Trade Agreement
SADC	-	Southern African Development Community
SADCA	-	SADC Cooperation in Accreditation
SADCMEL		SADC Cooperation in Legal Metrology
SADCMET		SADC Cooperation in Metrology
SADCSTAN		SADC Cooperation in Standards
SCC	-	Standards Council of Canada
SIM	-	Inter-American Metrology System
SMTQ	-	Standards, Metrology, Testing and Quality
SPS	-	Sanitary and Phyto-Sanitary
TBT	-	Technical Barriers to Trade
TCB	-	Trade Capacity Building
UEMOA	-	Union Economique et Monétaire Ouest Africaine
UNACOSUR	-	Union of South American Nations
UNECE	-	United Nations Economic Commission for Europe
UNIDO	-	United Nations Industrial Development Organisation
WTO	-	World Trade Organisation

Executive Summary

Standardisation and technical regulation systems are integral to business environment reform. Trade volumes are rising steadily. For much of this trade, compliance with standards and technical regulation is of paramount importance. The Quality Infrastructure (QI), which provides the evidence that products meet such requirements, therefore has to be acceptable to the market and regulatory authorities – otherwise suppliers will not gain market acceptance or be able to participate in global value chains.

Although no definitive internationally accepted structure for the provision of QI services exists, good practices have evolved that should be taken into consideration. Metrology, standards and accreditation are the fundamentals without which calibration and conformity assessment services cannot function properly. Governments need to establish a policy environment that establishes the responsibilities of government and gives space to the private sector for service delivery.

International recognition of QI organisations is vital for conformity assessment services to be accepted in the export markets. The National Metrology Institute (NMI) has to ensure that its calibration and measurement capabilities (CMC's) are taken up in the Key Comparison Database (KCDB) managed by the Bureau International des Poids et Mesures (BIPM). The National Standards Body (NSB) needs to be actively involved in international and regional technical committees relevant to the country. The National Accreditation Body (NAB) has to gain international recognition through the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) multilateral recognition arrangements (MRA).

Sustainability of established QI organisations depends on a number of key issues. Governments have a responsibility to provide funding for the fundamental QI institutions, i.e. metrology, standards and accreditation. 'Commercial' QI service delivery should be determined through appropriate market mechanisms, i.e. customers should have a choice as long as the technical competency of the service providers is ensured.

Food safety is an important element of the QI. Food regulations address elements of safety and quality subject to both the World Trade Organisation (WTO) Sanitary and Phyto-Sanitary (SPS) and Technical Barriers to Trade (TBT) Agreement. While National Standards Bodies (NSBs) in developing countries were sometimes allocated the responsibility for implementing mandatory food standards in the past, countries are now adopting an integrated approach in line with international best practices. This may include the establishment of food safety agencies. This changeover in responsibilities must be managed properly; otherwise it can lead to confrontations.

Technical assistance to national QI and regional QI systems are not separate issues, but must always be integrated in a holistic approach. Support can be provided in three areas: (i) Regional governance issues dealing with harmonisation of standards and technical regulation, and the mutual recognition of conformity assessment, (ii) establishment of a regional QI service for expensive services for which only a small national need exists in the countries of a region, and (iii) specialist regional bodies which are the link between the national and international regimes.

Good practices in delivering QI related technical assistance should be considered within three main interrelated phases:

1. Project preparation and management

- Good practice is to refrain from setting overoptimistic short term targets and to embed short term assistance in longer term objectives, including the beneficiary government's own long term policies and planning.
- Pivotal for project preparation is an in-depth analysis of the real needs of the country or region to gain a clear understanding of demand and supply of QI services, based on realistic assessments of the beneficiary organisations.
- Regional infrastructure cannot replace a selection of QI services at the national level, and specialised QI services at the regional level are only meaningful if they are accessible by all members or countries. Regional projects are more difficult to manage, interests of regional member countries are not always aligned, and asymmetries of economic development preclude a 'one fits all' approach.
- In order to ensure 'ownership', the project needs to be anchored in the right partner institution, directly responsible for the field covered.
- A balance needs to be found between the commitment of aid delivery, the absorption capacity of the recipient country and provision of highly technical services by the development partner whilst enhancing ownership through project steering committees and continuous information flows.

2. Strategic approaches to support quality infrastructure development

- QI service delivery has to meet a demonstrable demand for quality related services. Project design should take this into account, and if need be develop both demand and supply in parallel.
- Companies should be enabled to market their products successfully. Their products need to 'conform' to relevant standards and technical regulations, their prices should be 'competitive', with a return on investment and they need to 'connect' with markets. A value chain approach will help to identify the real needs of users of quality related services for key industries at the core of the project and increases the chance that all key challenges are addressed.
- Strengthening business service providers (intermediaries) is more effective and sustainable than direct service provision by the project.
- Chances of short term success in providing support to larger enterprises should not be the only goal. The SME sector is more difficult to reach, but in the long run may be more important for the country.

3. Support to quality institutions

- It is easy to underestimate the challenges of technical capacity development by a project. Institutional strengthening and having the appropriate legislative framework promulgated should be included as appropriate, even though they are much more demanding in terms of business practice reform and guiding draft/revised legislation through its political processes.
- A good way of promoting international credibility and anchoring institutions in international networks is 'twinning' them with more advanced peers in other countries.

- When equipping laboratories or other institutions, development partners should cooperate as much as possible to focus on a limited number of equipment suppliers in order to avoid subsequent problems with equipment maintenance.
- It is suggested to move from direct staff training towards institutionalizing training functions in key institutions. In addition, it is suggested to promote the fostering and exchange of expertise through 'communities of excellence'.

Donors and development agencies have specialised in specific elements of the QI. A division of labour may therefore yield much better results for the recipient countries, making coordination amongst the donor community increasingly important. This publication is an effort to facilitate such donor coordination.

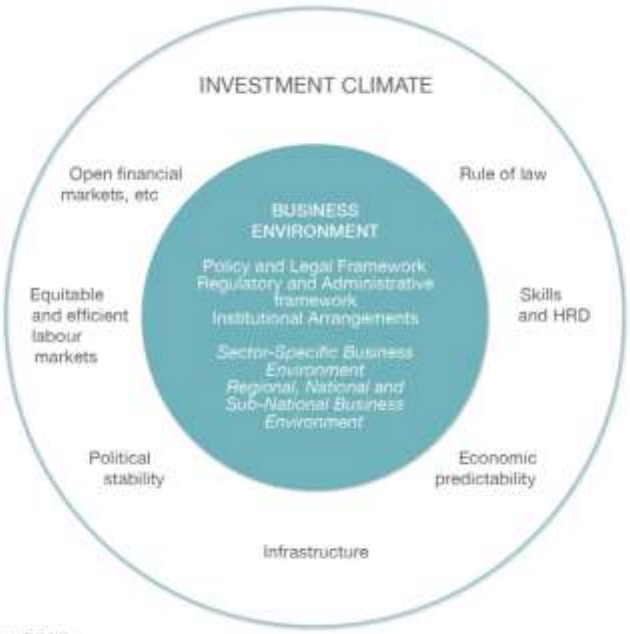
1 Business Environment and the National Quality Infrastructure (NQI)

A healthy business environment can be essential for growth and poverty reduction and a prerequisite for trade and competitiveness. The Quality Infrastructure (QI) is an important element of the business environment. Hence, business environment reform without considering QI reform may be incomplete.

1.1 Business Environment Reform[1] and Quality Infrastructure

The business environment can be defined as the complex of policy, legal, institutional and regulatory conditions that govern business activity. It is a subset of the investment climate and includes the administration and enforcement mechanisms established to implement government policies, as well as the institutional arrangements that influence the way key actors operate, such as government agencies, regulatory authorities, and business membership organisations – see Figure 1.

Figure 1: Defining the business environment



Source: Adapted from DCED

The business environment clearly has an influence on the development of the private sector, and thereby on economic growth and the generation of livelihood and jobs. Business environment reform promotes the development of markets that encourage healthy competition and enhances the effectiveness and sustainability of development interventions. Business environment reform is multifaceted, operating on many levels and involving a very wide range of stakeholders.

[1] Supporting Business Environment Reforms: Practical Guidance for Development Agencies, Donor Committee for Enterprise Development.

In today's world, markets are no longer domestic. Production of goods and services increasingly depend on specialisation and fragmentation into smaller tasks along global chains. As markets are becoming more globalized, products and many services flow freely across borders; the quality of products and services is therefore a key determinant of private sector performance as it allows companies to compete, conform to market requirements and connect to markets – see Figure 2.

Figure 2: Flow of products or services to global markets

Source: UNIDO

Standards define features and performance of products and processes, and how these interact with people and their environments. Standards convey information and provide means of communication and may be demanded by authorities (e.g. in the case of technical regulations for safety, health, environment) or the marketplace (e.g. for performance, quality).

In open and inter-connected markets, conformity with standards as well as the way standards are governed have similar impacts on private sector development as tax and custom policies and practices, labor laws and their administration and the overall quality of regulatory governance: governance of the quality infrastructure may increase costs and risks of doing business and impede or accelerate competition in the private sector.

Suppliers are increasingly challenged to provide products and services that demonstrably meet the requirements, specifications or standards at price levels that the market is prepared to pay. Such a demonstration may consist of inspection, testing, certification or any combination thereof by the supplier or a party independent from both the supplier and the purchaser. In either case, such processes will only be credible if the institutions providing the evidence are technically competent and acceptable to the market and regulatory authorities.

The institutions that provide such compliance evidence are collectively called the QI. Being the competent coordinators and authorities that set standards and technical regulations, the

organisations within a QI have an influential role; they can regulate access to production chains and markets, with positive or negative impacts on private sector development depending on how they are governed, and what their capacities are. This is easily apparent through a quick, non-exhaustive overview of how QI may interact with the business environment, as shown in Table 1.

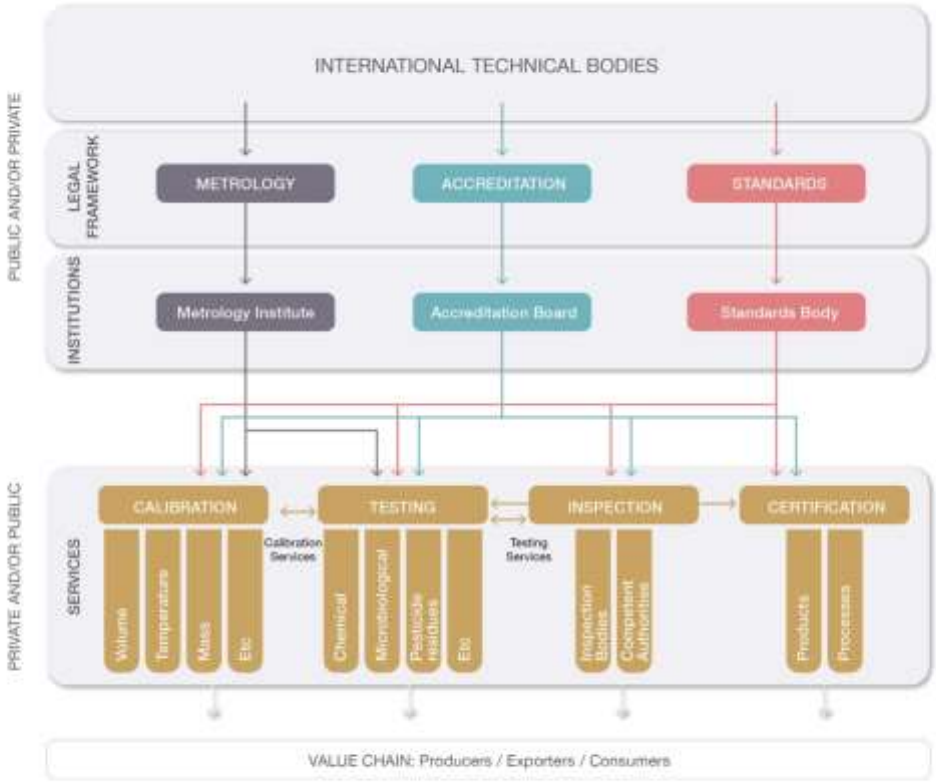
Table 1: Quality Infrastructure within the Business Environment

Quality Infrastructure within the Business Environment				
QI	**Regional/Global**	**National**	**Sub-national**	**Sectoral**
Key stakeholders	• Regional trading blocs such as EU, EAC, SADC, CARICOM, UNACOSUR, NAFTA, EAEC, ASEAN, etc. • Private sector entities at the top of global value chains • Regional metrology organisations such as AFRIMETS, APMP, COOMET, EUROMET, and SIM • APLAC/PAC, EA, IAAC, SADCA • ARSO, AFSEC	• Metrology Institute • Accreditation Board • National Standards Body / National Committee	• Provincial, regional, local inspection agencies (e.g. weights and measures) • Testing organisations • Certification organisations	• Line Ministries • Business associations • Sectoral regulators (e.g. Food and Drug Administration) • Testing organisations
Policy, legal and regulatory frameworks	Policies at the Quality-Consumer, Food and Environmental Protection and other policy interfaces	Quality policies and laws; technical regulations; mandatory standards; for instance, regulations at the quality-trade-industrial policy interface on age limits imposed on refurbished or second hand production equipment	Same as national	There may be coordination, capture, conflict of interest issues between national QI institutions and other public institutions, such as line ministries that are reflected in policy, legal and regulatory frameworks
Administrative frameworks and institutional arrangements	Technical regulations, mandatory standards, private standards; (e.g. residues in food and feed; management of chemicals, for instance REACH, CLP; contractual terms, etc.)	Public sector administrative practices that also govern QI institutions resulting in cumbersome, inappropriate practices and procedures; Capacity of national QI institutions with respect to qualified staff, financial resources, etc.	Same as national, although capacity constraints may be more pronounced at the level of organisations	Size of markets in small, fragile and low income economies may hinder existence of some types of institutions that need to service certain sectors, e.g. testing capacity may be limited only to a few sectors

1.2 The Quality Infrastructure - Overview

The QI is generally understood to be the totality of the policy, legal, regulatory and administrative frameworks and the institutional arrangements (public and/or private) required to establish and implement standardisation, metrology (scientific, industrial and legal), accreditation and conformity assessment services (inspection, testing and product- and system certification) necessary to provide acceptable evidence that products and services meet defined requirements, demanded either by authorities (e.g. in the case of technical regulation) or the marketplace (e.g. contractually or inferred)[2]. A diagrammatic view of the QI with its institutions and their inter-relationships is shown in Figure 3.

Figure 3: Elements of the quality infrastructure



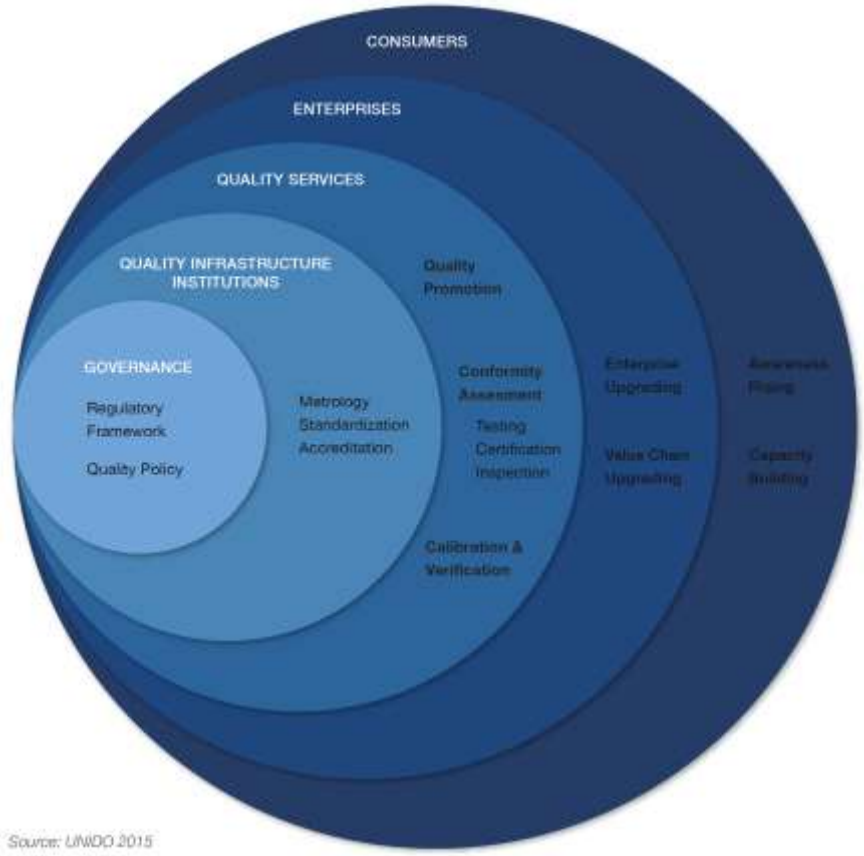
Source: UNIDO

It is important to understand that the QI, consisting of a number of institutions or service providers, can only function properly as a whole; the incompetence or absence of any one of the constituents will compromise the effectiveness and ultimately the efficiency of the whole system, thereby

[2] In the past and still in some areas, acronyms such as SMTQ, MSTQ, SQAM and others were/are utilised denoting various combinations of standards, metrology, testing, accreditation and quality. The more holistic concept of a Quality Infrastructure (QI) is rapidly replacing all of these.

negatively impacting the business environment. The foundational parts of a QI are the standards, metrology and accreditation organisations/institutions without which none of the other elements will be able to function properly. Because of their importance, it is imperative that governments play an active and continuous role in the establishment and sustainability of these institutions. They provide services which oftentimes are not targeted at a specific beneficiary that could be made responsible for their financing[3]. Governments should usually start by outlining their vision and strategy for QI development through a quality policy, as outlined in Figure 4 below.

Figure 4: From QI Governance to Consumers



In addition to the foundational parts of the QI supported by governments, the QI also consists of a wide variety of calibration and conformity assessment service providers for which a specific beneficiary can be readily identified, who then should pay for such services in full. Hence, even though governments frequently establish these service providers, this is a 'commercial' domain where the private sector should play an ever increasing role. These include calibration laboratories, testing laboratories, inspection bodies and certification bodies for systems, services, products and persons.

[3] Fast Forward: National Standards Bodies in Developing Countries, ISO Central Secretariat and UNIDO and Financing NSBs: Financial Sustainability for National Standards Bodies, ISO Central Secretariat and UNIDO.

At the international level a vast number of non-governmental and inter-governmental organisations have been established over the years to coordinate QI activities on an international basis. Some of the more important ones from a trade perspective are the following:

International Organisation for Standardisation (ISO), a non-governmental body that manages the development and publication of international standards for products and services not falling within the competence of the IEC and ITU. National standards bodies are the members.

International Electrotechnical Commission (IEC), a non-governmental body that manages the development and publication of international electrotechnical standards and administers four conformity assessment systems, IECEE, IECEx, IECQ and IECRE. National committees representative of the electrotechnical stakeholders of a country are the members.

International Telecommunications Union (ITU), a United Nations specialised agency that manages the development and publication of international telecommunication standards. Governments and scientific or industrial associations are the members.

Codex Alimentarius Committee (CAC), an intergovernmental body jointly managed by FAO and WHO that coordinates international recommendations and rules for food safety and quality. Governments (members of FAO and/or WHO) are the members.

International Plant Protection Cooperation (IPPC), an international treaty administered by the FAO that coordinates and publishes recommendations and rules on phyto-sanitary measures and plant diseases. Governments are the members.

World Organisation for Animal Health (OIE), an intergovernmental organisation that coordinates and publishes international recommendations and rules on the control of animal diseases. Governments are the members.

Bureau International des Poids et Mesures (BIPM), was set up by the Metre Convention. It is financed jointly by its Member States (i.e. governments) and operates under the exclusive supervision of the Comité International des Poids et Mesures (CIPM). Its mandate is to provide the basis for a single, coherent system of measurements throughout the world, traceable to the International System of Units (SI).

Organisation Internationale de Métrologie Légale (OIML), an inter-governmental organisation that coordinates the development of international recommendations and guidelines for legal metrology and measuring equipment. Governments are the members.

International Accreditation Forum (IAF) is a non-governmental organisation that coordinates accreditation activities and their recognition at the international level in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. National accreditation bodies are its members.

International Laboratory Accreditation (ILAC) is a non-governmental organisation that coordinates and manages accreditation activities and their recognition at the international level in the fields of laboratories and inspection. National accreditation bodies are its members.

Some of these and others have established a formal network to exchange information and promote coordination in the sphere of technical support to developing economies – see Box 1.

Box 1: Network on Metrology, Accreditation and Standardisation for Developing Countries

The Network on Metrology, Accreditation and Standardisation for Developing Countries (DCMAS Network) was established by the principal international organisations that have mandates to strengthen technical infrastructures and deliver capacity building in metrology, standardisation and conformity assessment (including accreditation). The 10 members (current) of the DCMAS Network are BIPM, IAF, IEC, ILAC, ISO, ITC, ITU, OIML, UNECE - WP9 and UNIDO. The aim of the network is: (i) to exchange information on the effectiveness and range of initiatives taken by the collaborating bodies; (ii) to provide a means of pooling expertise and for enabling the collaborating organisations to take advice from each other and to invite participation in events they organise under their own programmes and initiatives; and where agreed (iii) to exchange information and/or revise papers originally developed by DCMAS which set out the benefits and aims of Metrology, Accreditation and Standards in developing countries.

1.3 Quality Infrastructure and Good Governance

Good governance is perhaps the single most important factor in eradicating poverty and promoting development. It describes how public institutions conduct public affairs and manage public resources. In general, it is the process of decision-making and the process by which decisions are implemented (or not). Good governance is a crucial factor in shaping the framework conditions for a healthy business environment. The state provides the preconditions for an efficient administration, the rule of law, accountability, transparency of decisions, the fight against corruption and legislative tasks linked to the corresponding administrative structures, all of which act in favour of the socio-economic system and hence the business environment. Principles of integrity, objectivity, confidentiality, professional behaviour and due care should be the general foundations also applicable to the area of Quality Infrastructure.

These principles and practices apply in all aspects of any Quality Infrastructure. When testing a product to assess its conformity to standards, the principles of integrity, competence, and confidentiality apply. When developing a national standard, the principles of transparency, openness and consensus apply. The inspection function and market surveillance are also directly linked to objectiveness and confidentiality.

In respect of good governance at the meso level the government should promote and actively support:

1. Implementation of the relevant international and regional agreements, e.g. the WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement);
2. Participation of national stakeholders in international and regional QI organisations;
3. The development of capacities of QI organisations;

4. The training of staff at the national level; and
5. Networking of public and private institutions in relevant QI forums.

At the macro level, the government sets the framework conditions through legislation for the QI organisations, the technical regulation regime and implementation of the same. The government creates transparency by facilitating the provision of information (e.g. standards information and the WTO TBT National Enquiry Point), and by involving industry and consumer associations in QI deliberation and implementation activities. An effective and efficient Quality Infrastructure is therefore a concrete contribution to good governance.

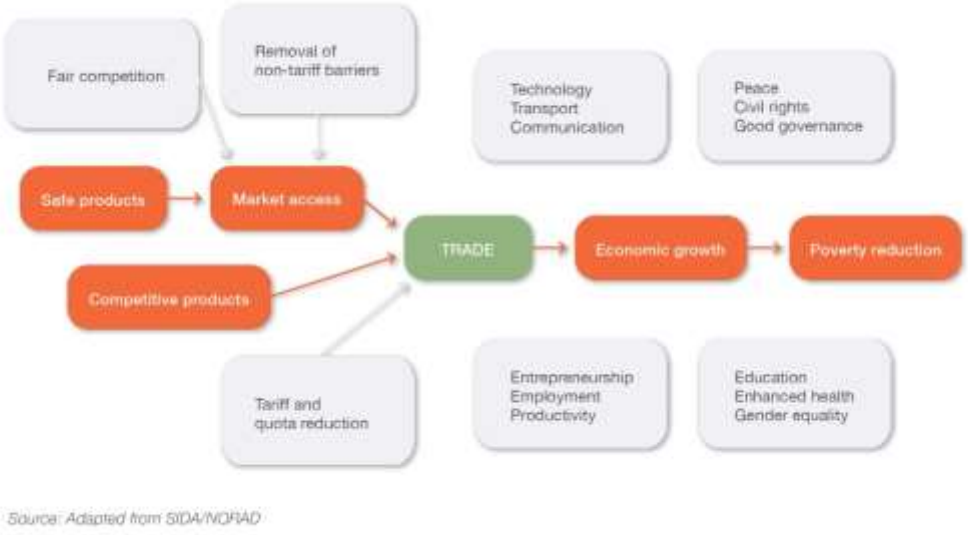
1.4 Quality Infrastructure and Trade

1.4.1 Trade and Economic Growth

It is generally recognised that enhanced trade should lead to economic growth, which could ultimately lead to poverty reduction. Trade helps an economy grow in several ways:

- It encourages economies to specialise and produce in areas where they have a relative cost advantage over other economies. Over time, this helps economies to employ more of their human, physical and capital resources in sectors where they get the highest returns, boosting productivity and the returns to workers and investors.
- Trade expands the markets local producers can access, allowing them to produce at a more efficient scale to keep down costs. Even in populous developing economies, low incomes often mean that producers' potential local market is small, so trading with the world is vital.
- Trade diffuses new technologies and ideas, increasing local workers' and managers' productivity. Technology transfers through trade and investment are particularly valuable for developing economies, which employ less advanced technologies and typically have less capacity to develop new technologies themselves.
- Removing tariffs on imports gives consumers access to cheaper products, increasing their purchasing power and living standards, and gives producers access to cheaper inputs, boosting their competitiveness by reducing their production costs.

Figure 5: Competitive and safe products, trade, economic growth and poverty reduction



Source: Adapted from SIDA/NORAD

One important factor essential for trade is that suppliers gain market access through competitive and safe products which are compliant with standards and technical regulations (see Figure 5 - highlighted). There are many other factors that also play a role such as infrastructure, finance, macro-economic and social policies, education, health, gender and many more. Some of these factors are also indicated in Figure 5. They are not less important than market access and competitive products, but will not be dealt with in any detail in this report.

The volume of exports of merchandise at the international level has been rising steadily over the past decade. Even the dip in volumes during the economic crisis of 2008/2009 has been overcome and volumes in 2012 have nearly regained the previous growth trajectory. The average growth for the period 2002 to 2012 has been an impressive 7 percentage points per annum[4]. Much of this merchandise is traded based on standards and technical regulations. These products should not have any negative effects on the health and safety of people and the environment, and product information should be truthful. A key issue is that all of this has to be assured in a way that allows for considerable (and ever increasing) trade volumes/speeds.

Rigid state driven command systems may in theory be able to ensure the safety and health issues, but they rarely do so because of conflicts of interest and lack of transparency, and especially because they are not able to accommodate the increasing volumes and speed of trade. The transactional costs they inflict are too high. Hence two-tiered systems (state or state-backed entities at the top, and market based conformity assessment providers below) as described in 1.2 above, have proven to be the more efficient systems to date.

[4] Estimated from data available on ITC database.

1.4.2 Standards, Technical Regulation and Trade

Of the ten main categories traded, nine are fully subject to public standards[5], and eight of them would be subject to technical regulations in some form or another – see Table 2. Hence standards and technical regulations influence our way of life in ways we oftentimes do not even notice, but their influence on trade is profound.

Table 2: The relevance of standards and technical regulations on top ten categories trade in the world

The relevance of standards and technical regulations on top ten categories traded in the world[6]				
Rank	Commodity	Value US$ ('000 000)	Stds*	TRs*
1	Mineral fuels, oils, distillation products, etc.	2,183,080	✓	✓
2	Electrical, electronic equipment	1,833,534	✓	✓
3	Machinery, nuclear reactors, boilers, etc.	1,763,372	✓	✓
4	Vehicles other than railway, tramway	1,076,831	✓	✓
5	Plastics and articles thereof	470,227	✓	✓
6	Optical, photo, technical, medical, etc. apparatus	465,102	✓	✓
7	Pharmaceutical products	443,597	✓	✓
8	Iron and steel	379,113	✓	
9	Organic chemicals	377,462	✓	✓
10	Pearls, precious stones, metals, coins, etc.	348,155		

*NOTE: Stds = Standards, TR = Technical Regulations

It has been shown empirically that conformity (including demonstration thereof) with standards or compliance with technical regulations does not significantly increase costs for the larger firms in OECD countries. For smaller firms the situation may be somewhat different, and in the case of firms in developing countries the situation is much more complex and costs vary tremendously across countries and depend on a range of factors[7]. It is true however, that multiple tests and/or certifications to determine compliance with technical regulation increase transaction costs and negatively influence trade. Reliable conformity assessment at the point of production will likewise reduce transaction costs because of less litigation.

It therefore seems logical that the harmonisation of standards and the mutual recognition of the associated compliance testing and certification should lower transaction costs, thereby enhancing trade and increase welfare. Producers on the other hand, frequently try to influence the development of national standards and technical regulation in particular, in order to gain an artificial advantage over foreign competitors or to keep them out of the market altogether. If they succeed, the resulting national standards that differ unnecessarily from international standards may tend to

[5] Public standards are normative documents developed in a consensus process open to all stakeholders and published by recognised standards organisations at national, regional or international level for general usage. Private standards in contrast, are developed by specific interest groups or organisations for their own, explicit purposes.

[6] International Trade Centre: https://www.trademap.org/index.aspx

[7] World Trade Report 2005, Exploring the links between trade, standards and the WTO, World Trade Organisation.

lower both trade and welfare. Only a clear national policy regarding standards can counter such trends. Such a policy goes a long way in supporting the establishment of a healthy business environment.

At the international level, agreements on tariffs have largely been negotiated and implemented. Now, squabbles regarding non-tariff measures (which include standards and technical regulation) have surfaced as the next major issue to be resolved within the world trading system[8]. Non-tariff measures are vast, complex, driven by multiple public policy motives and ever-changing. Recognition of conformity assessment results amongst economic actors is increasingly an economic necessity. An assessment of a range of bi- and multilateral government-to-government recognition agreements however, shows that commitments to mutual acceptance of conformity assessment results still tend to be limited in sectors including health, safety and environmental regulations. Governments are still pursuing national policy goals which frequently undermine trade, i.e. lead to a poor overall business environment. These goals may have been influenced by vested interests to limit competition or profit regulatory authorities or by interest groups concerned with safety lobbying for stronger national regulations than the prevailing international norms.

1.5 Quality Infrastructure and Poverty Reduction

Poverty reduction measures are generally intended to create shared prosperity and wellbeing as a means of ending poverty. This however, can only take place through economic growth, a well-designed business environment and the development of an industrial sector. Poor business environments may even have a disproportional negative effect on women-owned businesses, which are more likely to remain informal, extending the poverty trap. Experiences from the past decade show that shared prosperity was in most cases based on progress made in absorbing the labour force more effectively into higher income industrial jobs of a growing manufacturing sector. Extending this experience to the developing world means that it should likewise experience poverty reduction if the same changes can be brought about.[9]

Economic growth and industrial development have the potential to simultaneously increase employment opportunities and increase labour productivity. Technology is diffused through standards amongst others, and productivity is increased by their use. On the other hand, rigid or burdensome regulations and conformity assessment procedures effectively limit competition or market entry, choices for consumers are diminished, and this can have a negative price effect, especially for the poor. An effective QI will therefore be able to provide part of the fundamentals through which technology can be improved, productivity can be enhanced and economic growth is made possible – with the potential to lead to poverty reduction in the long run.

[8] World Trade Report 2011, Trade and public policies: A closer look at non-tariff measures in the 21st century, World Trade Organisation.

[9] UNIDO: Inclusive and Sustainable Industrial Development (ISID), Creating shared prosperity, Safeguarding the environment.

1.6 Quality Infrastructure and Environmental Management

Environmental concerns are high on the agenda of many countries, leaders and civil society as climate change is becoming a reality. In many countries environmental agencies have been established and given the authority to implement appropriate controls. Even at the international level, measures such as carbon trading are being discussed to bring down carbon dioxide emissions.

The vast majority of environmental laws and control measures are based on standards, technical regulation and physical measurements that need to be trustworthy. This is therefore an important field in which the QI can contribute directly to a healthy business environment in which enterprises can meet their environmental obligations in a cost-effective and internationally acceptable way.

1.7 Quality Infrastructure and Gender

Despite the potential positive impact of quality infrastructure development on gender issues and women's economic empowerment, this aspect has often been neglected by development partners in the past decades. Rightly, the topic has once again gained prominence and the gender-QI nexus is being increasingly explored.

Gender is a cross-cutting theme that needs to be considered at all levels of quality infrastructure development touched upon in this publication: quality-related policies and legislation, quality infrastructure institutions as well as conformity assessment bodies and enterprises/producers participating in global value chains.

In delivering technical assistance projects, development partners need to pay careful attention to gender aspects at the various stages of project management (project rationale, design and implementation) to ensure long-term impacts at the above-mentioned levels of quality infrastructure development. A first step to gain a better understanding of gender inequality is to work with disaggregated data, where possible. Available data on the share of women in QI-related occupations suggests that these are male-dominated on average.

Best practices on how to ensure a positive long-term impact on gender aspects in quality infrastructure are yet to emerge from development partners and QI institutions. More research is underway through different gender projects, but also the systematic mainstreaming of gender considerations into different technical assistance programmes.

1.8 Quality Infrastructure and Value Chains

The range of activities that brings a product or a service from its conception to its end use in a particular industry is referred to as the value chain, a term originally coined by Michael Porter. Value chains can be seen as a mechanism that allows producers, processors, and traders – separated by time and space – to gradually add value to products and services as they pass from one link in the chain to the next until reaching the final consumer (domestic or global).

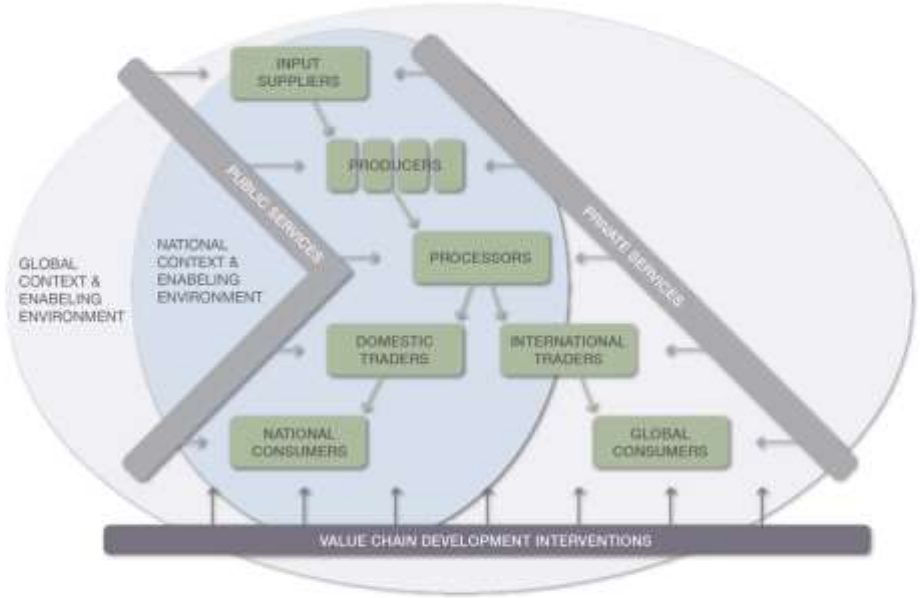
In the globalised marketplace it is rather unusual for a single company to perform all the activities from product design, production of components, to final assembly and delivery to the ultimate user. Original equipment manufacturers source components from a myriad of sub-suppliers frequently across many countries. Agents handle the marketing and sales, and specialised freight haulers ensure

the product is moved from the factory to the consumer. The manufacturers and suppliers draw from a range of technical, business and financial service providers, as well as public services. They depend on the national as well as global legislative context and socio-political environment. In a value chain the various business activities in the different segments become connected and to some degree coordinated – the value chain analysis covers the whole system in which the organisation operates (see Figure 6).

In each of the stages of the value chain the required QI services can be mapped (see an example of a mango value chain in Figure 6), and technical assistance can be designed to provide such services effectively and efficiently; otherwise the suppliers of products and services will not measure up to the minimum requirements in the world markets, i.e. remain in a sub-optimal business environment. Worse, if a country's QI does not meet international requirements, its producers may be unable to join international supply chains, e.g. entire ranges of products such as food of animal origin cannot be exported, at least to high income markets. By the same token, in economy-wide QI reforms, governments may be guided by applying a value chain approach to competitive industries, thereby ensuring more focused reform actions.

Utilising the value chain approach in this way will enhance the understanding of the business environment. Aligning QI technical assistance with this understanding will therefore help improve the business environment. As a result, value chains are increasingly utilised to guide the design of technical assistance programmes by development partners[10].

Figure 6: Value chain



Source: Adapted from UNIDO (2010). Value Chain Diagnostics for Industrial Development

[10] Diagnostics for industrial value chain development: An integrated tool. UNIDO.

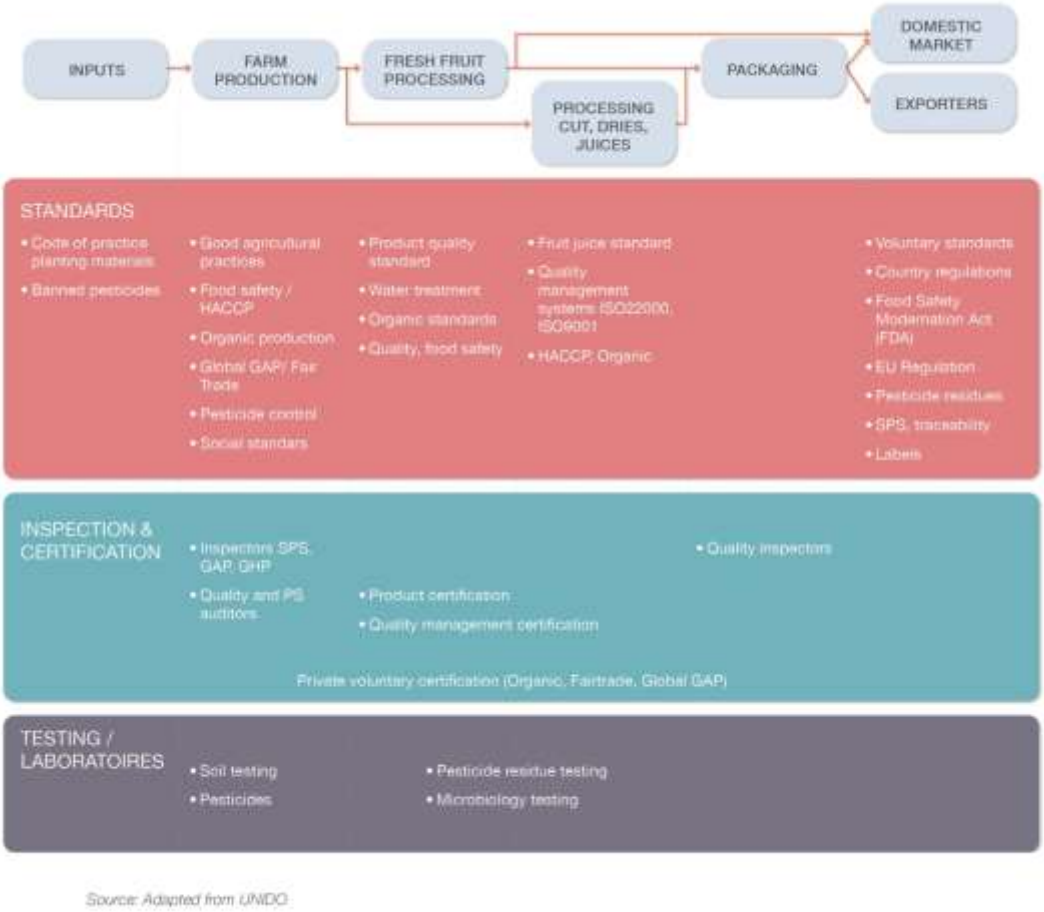
1.9 Quality Infrastructure Reform

Based on the previous sections, it is clear that Quality Infrastructure reform should be part and parcel of business environment reform. Establishing an effective and efficient QI takes time, requires a lot of funding and immense commitment by recipient countries. It is also very important to consider the context in which such reforms are implemented:

- Some countries (e.g. those in the influence sphere of the former Soviet Union) have an extensive Quality Infrastructure, both in the regulatory and institutional sense and in material terms – even though much of it may be outdated or inappropriate. This existing Quality Infrastructure is organised along principles that are mostly incompatible with current good practices. Reforming such existing, complex, expansive and rigid systems is a specific challenge: Such countries may have more capacity overall to develop a modern Quality Infrastructure than some less-developed ones, but resistance to reform is considerably higher.
- Some countries are somewhere in the middle, with very rigid systems (more or less inspired by former colonial powers or socialist systems) but limited implementation - hence with less capacity but also somewhat less resistance.
- Finally, some countries have very little (even though what they have may well be already incompatible with good practices) and thus resistance will be lower, but capacity to absorb technical support may be the real challenge.

'Getting it right first time' is therefore absolutely essential. Hence, good practices in defining development programmes, ensuring proper project management and continuously measuring output, outcome and impact are necessary to gain the maximum advantage for both the donors and the recipient countries.

Figure 7: Mango value chain



Source: Adapted from UNIDO

Over the years, donors and development agencies have spent millions to establish QI institutions in developing economies and to build capacity and competency in the same, and will have to keep on doing so for the foreseeable future. Fortunately, reviews of past and present QI reform projects are available, as is a vast body of literature on the subject. For this report, many of these have been screened and – together with questionnaires to donors and semi-structured interviews with individuals working in such projects – have provided much information leading to the identification of good practices for QI development and/or reform and related technical assistance, as well as the pitfalls to be wary of. Particular emphasis has been given to cross-validation of data and an assessment of the plausibility of results obtained. This report is a synthesis of this information, with the purpose of serving as a useful initial guide for development agencies that are planning and managing such projects or considering doing so. If needed, more detailed information can be obtained from various publications and on-line resources, some of which are listed at the end of this report.

2 Good practices of Quality Infrastructure Development at National Level

In this section, guidance is provided on what a well-developed QI should look like – based on known international good practices and national examples.

2.1 Good Practices in Quality Policy Development

QI is a complex issue, and no single, internationally identifiable practice has emerged, nor is likely to. There are many possibilities, customs and practices that have to be considered. It is clear however, that the QI is in the first place a government responsibility, especially as regards metrology, standards and accreditation. The private sector has an important role to play, but this cannot really come about until the QI fundamentals are in place.

Figure 8: Quality policy cross-cutting domain

Source: UNIDO

It is therefore not surprising that governments are increasingly under pressure to modernize their QI, and the basic government instruments to facilitate this would be a national policy and associated legislation. It can be argued that such a National Quality Policy should be a prerequisite for a technical support programme, because if the overall strategy for development is unclear or unknown, any development work may end up being ineffective. On the other hand, developing and promulgating a Quality Policy is a long term endeavour, and many areas of QI development can be successfully undertaken without a Quality Policy in place.

2.1.1 Quality Policy

The Quality Policy articulates the government's intentions regarding QI development in the country. The Quality Policy does not exist in a vacuum; it has to be promulgated within the context of industrial development, export promotion, trade promotion or similar government policies and strategies – see Figure 8 above. To be complete, the Quality Policy should also deal with the very important subject of technical regulations, as this is closely linked with standardisation, especially in

developing countries. It is not so much standards that lead to unnecessary trade restrictions, but primarily technical regulations as they are mandatory by law.

Box 2: The Standards Malaysia story

Malaysia started developing its QI in the 1960s as it moved from an agricultural to an industrial economy and the government established the Standards Institution of Malaysia (SIM) in 1966. SIM developed national standards and established facilities for product testing and certification. In 1975 SIM was merged with the National Institute of Scientific and Industrial Research (NISIR) as the Standards and Industrial Research Institute of Malaysia (SIRIM), creating synergy between standardisation and technological development to support economic development.

In 1993 SIRIM was authorised to undertake commercial operations through the formation of joint ventures or wholly owned subsidiaries, which it did for conformity assessment. The SIRIM Council of 24 members was replaced with a smaller SIRIM Board of 13 members of which six were from the public sector and seven from the private sector. The new Board structure facilitated greater accountability and efficiency and further strengthened the linkages between SIRIM and industry.

In 1996, the SIRIM Act 1975 was replaced by the Standards of Malaysia Act 1996. SIRIM was corporatized and the Department of Standards Malaysia was establishment as a new agency within the Government. Corporatised SIRIM undertakes metrology, inspection, testing and certification activities over and above its research and development work. With these developments, conformity assessment became totally commercialised/privatised in Malaysia although some of it owned by government.

The Department of Standards Malaysia (DSM) took over the statutory role in standardisation and was made responsible for accreditation in Malaysia. In 2006, DSM was re-branded as Standards Malaysia, the identity under which it is today operating. Standards Malaysia publishes, promulgates and promotes the use of Malaysian Standards (MS) and manages the national accreditation schemes in accordance with international practices. Standards Malaysia does not develop standards, and appoints SIRIM and others as its Standard Development Organisations: Standards development is therefore now fully decentralized in Malaysia, whereas standards publication is legally the sole mandate of Standards Malaysia.
Source: Optimizing Quality Infrastructure: Options for Pakistan - Insights and Experiences from Malaysia, Turkey and Vietnam, UNIDO

A well-developed Quality Policy can have a positive impact on industrial development and as such will have a marked effect on trade. It is incumbent on any government therefore to develop the Quality Policy carefully, endeavouring to align it with country realities (i.e. resource constraints, political structures, business environment, etc.), market demands, international good practice and formal agreements. It is also important that the policy is reviewed regularly (e.g. in a 5 year cycle), as the standardisation and technical regulation sphere is very dynamic at the moment, and goal posts can move considerably in fairly short time spans – see Box 2: The Standards Malaysia Story.

2.1.2 Quality Policy Content[11]

Good practices regarding the content of a well-structured Quality Policy are emerging and include:

a. Statement of commitment of the government.
b. In-depth analysis of the policy environment in which the Quality Policy has to be established.
c. Identification of the current QI in the country, especially its strengths, weaknesses and challenges. The views of the clients of the QI institutions, especially the private sector, should be sought, given that the QI institutions may be unable to provide objective information.
d. Analysis of the technical regulation regime, and custom and practices amongst the many responsible Ministries. The technical regulation regime should be benchmarked against the WTO TBT Agreement and practices of major trading partners.
e. Definition of policy objectives, i.e. the main issues identified in the analysis that need to be addressed.
f. Outlining the QI structure of the future. This should deal with all the public entities and provide space for private sector involvement.
g. Development of a common approach to technical regulation to be followed by all Ministries.
h. Definition of responsibilities of government, the private sector, NGOs and development partners.
i. Legislative review programme to align legislation with the policy objectives.
j. Implementation schedule and responsibilities, including the coordination and oversight responsibility.

2.1.3 Development Methodology

In many countries government policy development follows a specific path, often prescribed by government procedures. Nevertheless, the following activities have proven to render good results:

a. Designation of a focal point in the relevant Ministry – a good call would be the Ministry responsible for the implementation of the WTO TBT Agreement in the country, or if the country is not yet a member of the WTO, then the Ministry responsible for trade. The focal point should be a senior official supported by a working group of senior officials from other stakeholder Ministries, especially those that develop and implement technical regulations. It might be necessary to obtain Cabinet approval for the development of the Quality Policy and for the working group beforehand.
b. Development of a 'Concept Paper' or 'White Paper' that sets out the issues that need to be addressed, and provides some early recommendations. This Concept Paper should be distributed to all the relevant Ministries, as well as the organised private sector (i.e. large companies through to the SME sector), for their perusal and comment. Personal visits to explain the complexity of the issues are useful.
c. Organising a workshop with stakeholders, both public and private, to debate the Concept Paper and to provide guidance on the way forward. The outcome of such discussions should then be utilised to firm up the text of a first draft Quality Policy.

[11] Kellermann MG, Thoughts on a National Quality Policy, PTB.

d. The draft Quality Policy should be circulated widely for public comment. The comments should be collated by the working group into a final draft Quality Policy to be discussed at a public validation workshop, or series of workshops.
e. After the validation workshop, the now final draft Quality Policy can be introduced into the political level for consideration and final approval by Cabinet or Parliament as appropriate. Thereafter, the approved Quality Policy should be made available as a public document of government.

2.1.4 Implementation of the Quality Policy

The Quality Policy will not be useful if not implemented, and implementation usually takes a number of years. Hence, it is good practice that a high-level implementation plan, including associated implementation and oversight responsibilities as well as budgets, is developed at the same time as the Quality Policy. It would even be useful to submit the Implementation Plan together with the draft Quality Policy to the political level. The QI is a cross-cutting issue and technical regulation even more so. Hence, many Ministries and their agencies will be involved in its implementation. This needs to be clear from the start and commitments to do so have to be secured at the highest political level.

It is inevitable that public QI institutions undergo heavy re-engineering, implementing changes to their organisations, responsibilities, funding, etc. The legislation will most likely have to be totally reviewed or developed from scratch. All of this needs to be coordinated at the highest level possible, and will require significant public funding. The oversight responsibility must therefore be clearly identified, with accountability up to at least ministerial level, or better still, the government.

2.2 General Challenges in Reforming the Quality Infrastructure

2.2.1 Legal and Institutional Arrangements

The basic elements and related services that make up the QI are shown in Figure 3 (on page 15) and Table 3 below. At the international level, independent organisations look after the interests of each, in some cases even more than one, e.g. international standards or accreditation. Such independence is mirrored in most developed economies. In developing economies it is frequently impractical or too resource intensive in terms of finances, buildings and skilled staff to establish independent organisations for each of the functions. Hence, some of the functions are frequently combined. This is not an issue as long as specific conflicts of interest are considered (e.g. accreditation and conformity assessment in the same organisation), and if governance, management and business model risks and concerns are appropriately addressed.

2.2.2 Standards Development and Conformity Assessment

The process of developing consensus-based standards at the international level by ISO, IEC and others are largely regulated by the WTO TBT Agreement and ISO/IEC Directives[12]. The body of international standards is comprehensive and easily accessible. A similar situation exists in the more developed economies. It is however difficult to obtain a complete picture in many developing

[12] ISO/IEC Directives, Parts 1 and 2: Procedures for technical work, ISO Central Secretariat and IEC Central Office.

countries, where the processes may vary widely. In addition, as technology develops at an ever increasing pace, the approaches to standardisation are also evolving quite rapidly at the international level, creating shifting goal posts that challenge developing economies.

Conformity assessment is not a trade barrier as such, but an everyday reality in commercial transactions; however, conformity assessment arrangements can have important implications for competitiveness and market access. A number of international and regional systems have developed over time with the objective of establishing networks of conformity assessment bodies (mostly within the private sector) whose competence can be relied upon by all members and users. In developing countries, however, the provision of conformity assessment services is often inadequate, costly, government-driven and centralised.

While developments in these two areas are taken into account in developed economies because of the very active private sector participation in effective public-private partnerships, this is generally not the case in developing countries. Hence, governments in developing countries are increasingly under pressure to develop or modernise their QIs and provide space for private sector participation.

2.2.3 Cross-cutting Challenges

Developing countries often face challenges in implementing best practices in QI development. It is one thing for the development partners to establish QI institutions, appropriately train their staff and provide expensive equipment, but it is quite another for the recipient country to maintain the same. Cross-cutting challenges to consider in any development work include the following:

a. The re-engineering of the QI typically requires a drastic review of the legislative instruments. In developing countries this is a time-consuming process. Yet, without the review of outdated or insufficient legislation, or the development of new legislation, the QI cannot be transformed into an effective support service for the benefit of the whole country. Generally, any legislation older than about 5 years should be reviewed, and anything older than 10 years must be reviewed.
b. Metrology, standards and accreditation are activities which are rarely self-financing in a developing country context.
c. Hence commitment by government for adequate and long-term funding through the national budget is an absolute necessity.
d. The QI organisation service delivery is heavily dependent on trained and skilled personnel. Hence, development partners spend large sums on training. These skilled people are then often frustrated by civil service remuneration packages that do not acknowledge their competencies. They leave the public QI institutions which are then left without the necessary skills and may even lose accreditation and/or recognition. Means should be found to remunerate such personnel adequately even within a civil service context.
e. Governance in the form of Councils or Boards is important as they have fiduciary and strategic responsibilities regarding the QI institutions. Custom and practice in developing economies is to fill these with representatives from the public sector, i.e. Ministries, while the private sector remains underrepresented. This alienates the QI institution from the very sector they need to serve. The challenge is to get prominent industrialists to serve on Councils or Boards: they bring business acumen, act as marketing agents in the private sector, and have a far better idea of the strategies the QI institution needs to pursue in order to render a proper service.

Table 3: Elements and services of a quality infrastructure

Elements and services of a quality infrastructure			
Element		Description of the service	Institution involved
Metrology		The science of measurement. Metrology can be subdivided into: • *Scientific metrology*: the development and organisation of the highest level of measurement standards • *Legal metrology*: the assurance of correctness of measurements where these have an influence on the transparency of trade, law enforcement, health and safety • *Industrial metrology*: the satisfactory functioning of measurement instruments in industry, production and testing laboratories	• National Metrology Institute (NMI) • Legal Metrology Department (LMD) • Calibration laboratories The NMIs and LMDs are mostly public organisations. Calibration laboratories may be public or private – the trend is towards private.
Standards		Publication of a formal document (the standards), generally developed by consensus, containing the requirements a product, process or service should comply with. Standards are essentially voluntary in nature and producers can choose when to use them. But once standards are used in contracts or are referenced in technical regulation, compliance becomes obligatory.	• National Standards Body (NSB) • IEC National Committee (NC) • Sectoral standards development organisation (SDO) • Industry based standards development organisation Most NSBs are public or not-for-profit organisations. SDOs are mostly from the private sector, but do not exist in many countries.
Accreditation		Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.	• National Accreditation Body • Industry-based Accreditation Body The NABs are either public or not-for-profit organisations. Industry-based accreditation bodies operate in very specific schemes on a world-wide basis.
Conformity Assessment	Inspection	The examination of a product design, product, process or installation and the determination of tis conformity with specific requirements or, based on professional judgment with general requirements. Inspection is often conducted on consignments – for example import inspection – to ensure that the entire consignment is equivalent to the product sample tested.	• General inspection agencies • Import inspection agencies Inspection agencies can be public or private entities.
	Testing	The determination of a product's characteristic against the requirements of a standard. Testing can vary from non-destructive evaluation (e.g. X-ray, ultra-sound, pressure testing, electrical, etc. where after the product is still fit for use) to a total destructive analysis (e.g. chemical, mechanical, physical, microbiological, etc. where after the product is no longer fit for use) or any combination thereof.	• Test laboratories • Pathology laboratories • Environmental laboratories Laboratories can be public or private entities.
	Certification	Third-party attestation related to products, processes, systems or persons. NOTE 1 Certification of a management system is sometimes also called registration. NOTE 2 Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.	• Product certification bodies • System certification bodies • Personnel certification bodies Certification bodies can be public or private entities.

2.3 Good Practices for Metrology

2.3.1 National Metrology Institute (NMI)

Primary responsibilities

The NMI has the prime responsibility of ensuring that any measurement made in a country can be traced to the International System of Units (the SI) via international standards, thereby helping to facilitate acceptance of products, processes, measurements and testing in the local and foreign markets. This is done through the establishment and maintenance of national measurement standards that are either primary (i.e. fundamental scientific realizations that have been subject to international comparisons) or national measurement standards traceably calibrated to primary measurement standards held by another NMI. These national measurement standards are then utilised to calibrate the working standards of calibration laboratories, legal metrology departments and others in order to complete the traceability chain right down to the users of measuring equipment.

In the past these measurement standards dealt only with physical quantities such as mass, temperature, length, pressure and the like, but now chemical metrology has become an important part of the NMI activities, and one that even developing countries need to consider seriously. Together, this can be very expensive; in addition to the expensive equipment, appropriate facilities with sophisticated air-conditioning and uninterrupted power supply, as well highly skilled staff and adequate and continuous government financing, have to be available. This makes the establishment of an NMI a very challenging prospect for any developing country, but one that cannot be ignored.

Organisational form

The following possibilities can be contemplated for the establishment of an NMI:

a. A centralized and independent organisation under the auspices of a relevant Ministry;
b. A properly separated and identifiable division within a larger scientific institution such as a national research organisation, but with its own budget and management;
c. A properly separated and identifiable division within the National Standards Body;
d. A combination of NMI and legal metrology responsibilities within an independent metrology department (however named); and
e. A decentralized organisation with a multiplicity of institutes all having the status of an NMI. It is usual practice for one institute – often holding the national measurement standards for the most basic units – to be known as the NMI and for other institutes to be 'designated' for particular measurement standards that are not available at the NMI. Such institutes are referred to as Designated Institutes (DIs).

The optimum choice would be a centralized and independent NMI, which may devolve the maintenance of specific national measurement standards to certain other laboratories without those having the status of an NMI. This however, is an expensive option. Of the other possibilities, (b), (c) and (d) are probably the most attractive for a developing economy as some economies of scale are possible. The last option is usually not an attractive one for a developing economy to follow, and is rare even in developed economies.

International recognition

It is important that the NMI becomes an active member of the BIPM and relevant regional metrology organisations (e.g. AFRIMETS, APMP, COOMET, EUROMET, and SIM). It is through these liaisons that the country's measurement system will gain international recognition. The list of its Calibration and Measurement Capabilities (CMCs) needs to be recognised through key comparisons and peer evaluations, and thereafter listed in the key comparison database (KCDB)[13] managed by the BIPM. Without such CMC entries, the country's industry will find it difficult in the long run to gain acceptance of measurement results in the international markets.

Legal arrangements

It is proper that the metrology system is given legal certainty through a legislative instrument. Such legislation should identify the national measurement units (e.g. the SI System), the responsibility to establish and maintain the national measurement standards, and establish the NMI with its responsibilities, governance, finances and activities. The OIML has published a guidance document[14] on developing such legislation and there are many good pieces of more recent legislation available all over the world from a variety of legal systems that could serve as examples.

2.3.2 Legal Metrology

Primary responsibility

Legal metrology (or weights and measures) is usually the first of the QI to be established in any country, and also the one with the longest history – going back at least 3000 years. Traditionally, legal metrology dealt with measurements in trade, ensuring that customers are given the correct amount of product traded on the strength of weight, volume, length, area, etc. In the past decade these concepts have slowly been extended to law enforcement, health and safety and environmental controls. Legal metrology controls[15] are generally based on the type or pattern approval of the measuring equipment in question against a legal metrology regulation, followed by calibration and verification during commissioning and at predetermined intervals thereafter[16]. This is to ensure that the equipment is capable of delivering results within specified tolerances, and continuously so.

Organisational form

Legal metrology is a form of technical regulation. Hence, most Legal Metrology Agencies are either government departments or public institutions given the authority to enforce legal metrology requirements. In developed economies they are usually independent, whereas in many developing economies legal metrology is combined with scientific metrology (see 2.3.1) or other regulatory

[13] The KCDB comprises two main sections: one contains information about the internationally recognised Calibration and Measurement Capabilities (CMCs) of the participating institutes, and another contains information about the key and supplementary comparisons supporting these CMCs. More information can be obtained on the BIPM website: https://www.bipm.org/en/home

[14] OIML D1, Elements for a law on metrology, OIML.

[15] OIML D3, Legal qualification of measuring instruments, OIML.

[16] Calibration and verification are complimentary concepts. In calibration the difference between the actual measurement and the true value is determined, and in verification this difference is verified to be within legal limits.

authorities. In smaller developing economies in particular, skilled metrologists are not in plentiful supply, and scientific metrology is only a small operation compared to legal metrology. But, differences have to be managed: Legal metrology is a regulatory function requiring a very specific type of expertise, whereas metrology is a scientific endeavour requiring an entirely different type of specialists, even though the technology is the same for both.

In developing economies, the Legal Metrology Agencies may have to provide all the legal metrology services, with the exception of type approval testing of measuring equipment that can be based on international test reports underwritten by the OIML. As the economy develops, some of the services can be usefully provided by private sector metrology organisations under the supervision of the Legal Metrology Agency, for example calibration and verification of measuring equipment. The legal framework to devolve such responsibilities needs to be carefully developed and promulgated, because the accountability remains with the Legal Metrology Agency.

International recognition

Due to the fact that legal metrology is a regulatory function, it does not need to pursue international recognition in the same way that scientific metrology or accreditation do for example. But there are other issues that should be carefully considered. In the first place, the legal metrology department should become a member of the OIML, the international organisation established to harmonise legal metrology world-wide. The OIML publishes a large number of recommendations regarding legal metrology that any country would be prudent to adopt as national regulation, thereby facilitating trade where quantities matter. In addition, the OIML manages an international system of mutual recognition of test results for measuring equipment, facilitating type approval in any country without having to re-test such equipment.

Legal arrangements

Without decent legislation, legal metrology cannot be implemented effectively. The OIML has published a guidance document, OIML D1[17], on developing such legislation and there are many good pieces of more recent legislation available all over the world from a variety of legal systems that could serve as examples. In some countries metrology and legal metrology are combined in one piece of legislation, and it is also the way in which the OIML guidance document is set out. In practice, this may not always be the optimum solution. It is good practice to deal with a single issue in legislation and not two. Hence it may be better to separate the metrology legislation from legal metrology legislation, even though the organisation could be the same. The focus of the two pieces of legislation is quite different.

The primary legal metrology legislation is in the first place 'enabling legislation', i.e. it creates the legal metrology framework and establishes the legal metrology agency. The technical details for the measurement equipment that need to be regulated are then promulgated as second tier legislation (e.g. regulation). In this way the technical requirements can be updated in a timely manner without having to go through the parliamentary process every time. The OIML has published a large body of recommendations that should be utilised as the basis for such second tier legislation.

[17] OIML D1, Elements for a law on metrology, OIML.

2.3.3 Common Challenges in Metrology

Metrology is a technologically intense and expensive business. Common challenges include the following:

a. Measurement standards require proper laboratory space and functioning environmental controls. Development partners are willing to provide equipment, but sometimes the recipient country has to provide the space and environmental controls. Mobilising the country contribution can be a real challenge.
b. A key issue is the choice of national measurement standards and their accuracy class. Knowledge regarding the needs of industry, testing laboratories and the public sector are extremely important in guiding such decisions. It is of no use if the national measurement standard is of a lesser accuracy than what industry requires.
c. The opposite to (b) above is also a real challenge, namely the over-specification of measurement equipment (either by the recipient organisation or the supplier) far above the needs of the economy or the realistic ability of the NMI to operate. Over-specification has a series of disadvantages: (i) The equipment is much more expensive and more difficult to maintain; (ii) much more demanding laboratory environmental requirements are needed; (iii) the equipment needs much higher expertise to operate at its full potential; (iv) because there is no need, the equipment is never used and no expertise is built up, and (v) operating at the low uncertainties requires very careful metrology to deal with the influence factors.
d. Measurement standards need to be properly maintained and have to be periodically calibrated or compared through regional and/or international comparisons. Custom procedures are frequently a major issue in moving such instruments from one country to another. Sometimes sending equipment under personal supervision of a metrologist is the only means of doing so.
e. Routine calibration for industry is a service that the private sector often can provide more efficiently than any public calibration laboratory, provided there is sufficient demand. The metrology system policy and legislation should therefore make space for such private sector laboratories to be established. As long as they are appropriately accredited to ISO/IEC 17025 and their working standards traceably calibrated to the national standards, they should be fully recognised by the authorities.
f. Larger companies may establish their own in-house metrology laboratories. The same requirements for accreditation to ISO/IEC 17025 would apply to them as well, if authorities are to accept their results.

2.4 Good Practices for Standards

2.4.1 National Standards Body (NSB)[18]

Primary responsibilities of NSB

The National Standards Body (NSB)[19] has the primary responsibility to oversee the development of national standards and to publish the same. The NSB should ensure that standards development

[18] Fast Forward, National Standards Bodies in Developing Countries, ISO Central Secretariat, UNIDO.

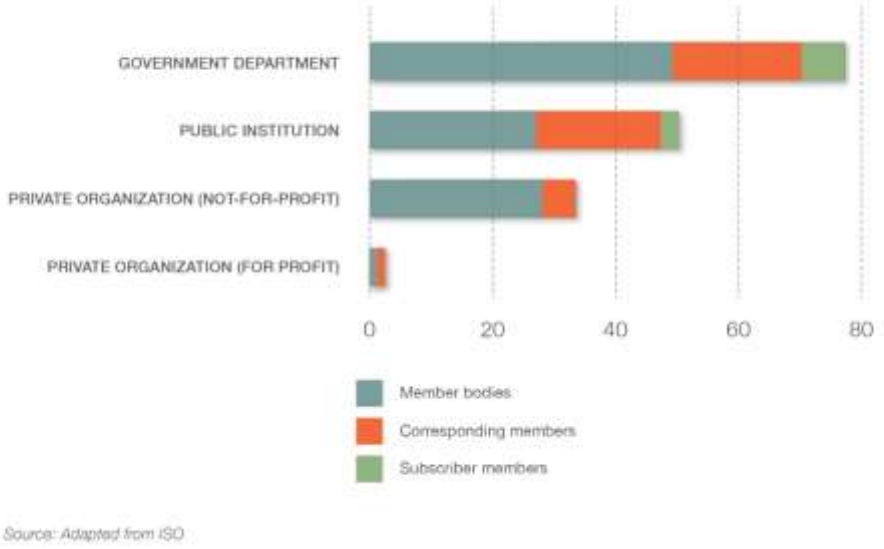
[19] It is important to take into consideration the basic differences of ISO and IEC in this regard. The members of ISO are the bodies most representative of national standards development and publication in a country, in

processes in the country meet the requirements of Annex 3 of the WTO TBT Agreement if the country is a WTO member or if it intends to become one.

Standards development

Standards development takes place in technical committees which are representative of all stakeholders. The NSB can establish and manage these committees but does not necessarily have to do so; this can also be left to other Standards Development Organisations (SDOs) that are recognised as such by the NSB – see Box 3. But, the NSB should be the apex organisation that publishes national standards, even enjoying a legal monopoly for doing so.

Figure 9: Organisational form of ISO members



Source: Adapted from ISO

Standards information

Finally, the NSB should operate a well-equipped standards information centre, where users can obtain up-to-date information on international, regional and national standards, also of main trading partners, or are able to purchase the same. Hard copies of standards need to be available (the most cost effective is a print-on-demand system), but electronic copies and efficient web based information services are essential in the modern era. The standards information centre is often the

other words, the National Standards Body (NSB). The members of IEC on the other hand are National Committees that are fully representative of national interests in the fields of activity of the IEC (see also Figure 10). In most developed countries these are two totally different constructs, but in many developing countries the NSB assumes the role of the Secretariat for the IEC National Committee – allowed for by the IEC membership criteria which are fairly flexible in this regard. The other big difference in the activities of ISO and IEC is that ISO does not manage any international certification schemes, whereas the IEC administers four conformity assessment systems: IECEE, IECEx, IECQ and IECRE.. The way in which these differences are dealt with in a developing country will be therefore be determined by custom and practice, by available resources and the stature of the NSB in industry.

'designated national enquiry point' for the country required under the WTO TBT Agreement, but not necessarily so.

Organisational form

The NSB can take on many forms, and this will depend to a large extent on the custom and practice of the country. It can be a government department, a public institution (i.e. statutory body), or a private organisation either 'not-for-profit' or 'for-profit'. An analysis of ISO members (see Figure 9) indicates that most ISO members are still government departments, followed by public institutions. However, the numbers of the not-for-gain private NSBs have increased over the past decade, now equalling public institutions in the case of member bodies. For-profit NSBs have virtually disappeared. A survey conducted by IEC in 2014 shows a similar trend among NCs (see Figure 10) with representation from the public sector being the highest. However, a variety of other stakeholders are also represented. These tendencies indicate the 'public responsibility' of NSBs and NCs, yet also show that governments are slowly withdrawing from service delivery, leaving it to specialised organisations that can respond rapidly to market pressures.

Another serious consideration is whether the NSB should provide conformity assessment services in addition to its primary responsibility regarding national standards. In developed economies, the NSB frequently does not do so, relying on sales of standards and/or government funding. In the EU for example, most NSBs operate in this way, as required by EU statutes. In the rest of the world, and especially in developing economies, NSBs provide conformity assessment services as a national necessity and to obtain funding for their standardisation work. There is no conflict of interest in this as long as the NSB is not involved in accreditation activities or has a legal monopoly. Another possibility would be for the NSB to be combined with the national accreditation body (e.g. SCC in Canada, DSM in Malaysia – see 3.1.2) in which case it would not be allowed to provide conformity assessment services.

In many countries NSBs are still involved in the administration of technical regulations. At one time this was considered useful, as technical expertise relating to standards and technical regulation was a scarce commodity in many developing economies. It was also the way in which things were arranged in the former Soviet Union, and hence followed by those countries that were aligned with it. Such a construct is no longer tenable as it is considered a conflict of interest, and is seen as a way for the NSB to extract rent instead of providing a service that is wanted by industry. Countries where the NSB is involved in such activities should seriously consider separating technical regulation administration from its NSB – the NSB can retain its conformity assessment services and can become the service provider of preference to the regulatory authorities.

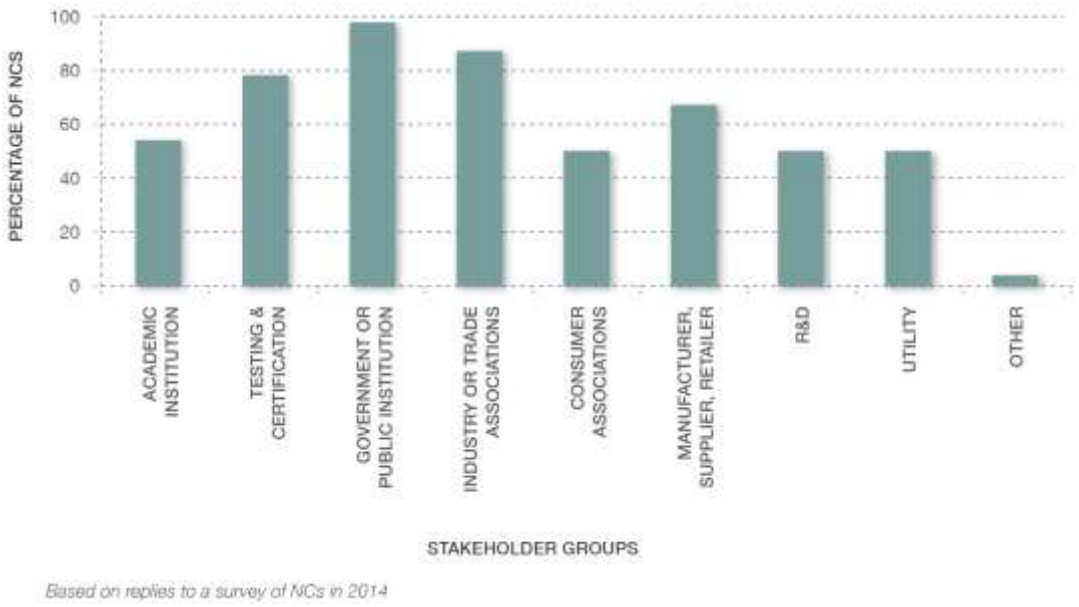
International recognition

Formal recognition systems such as those established for metrology and accreditation do not exist for standards. But NSBs of developing countries should become active members of at least ISO, IEC, ITU and Codex Alimentarius Commission (CAC). Such membership can be obtained at various levels, e.g. member, correspondent member and subscriber member in the case of ISO, or full member and associate member in the case of the IEC. Each level of membership confers certain privileges, full membership obviously the most. Privileges include voting rights in the General Assembly (ISO) or

Council (IEC), membership status in Technical Committees and the rights to adopt ISO and IEC standards without infringing their copyright[20]. The latter is especially important for developing countries, as they are mostly 'standards takers'.

Similar arguments hold true for regional standardisation organisations, with the difference that these are mostly political constructs of regional trading blocs such as the EU, EAC, SADC, CARICOM, UNACOSUR, NAFTA, EAEC, ASEAN, etc. In this case, membership is mostly automatic for the NSBs to represent their countries, but their level of active involvement still needs be managed.

Figure 10: Stakeholder representation on NC management boards



Legal arrangements

It is proper to provide legal certainty for the status and usage of national standards through appropriate legislative instruments. Hence, in most countries where the NSB is either a government department or a public organisation, standards legislation in some form or another has been promulgated. In countries where NSBs are private organisations there is at least a contract or memorandum of understanding in place between the government and the NSB (e.g. Germany, Costa Rica, etc.). The legislative instrument should identify as a minimum the legal status and usage of

[20] ISO and IEC are private not-for-profit international organisations that obtain a large proportion of their funding from the sale of international standards that enjoy international copyright protection. Members of these two organisations are authorised to adopt their international standards as national standards on certain conditions contained in formal agreements with ISO and IEC. If you are not a member (in the case of both) or participant in the IEC Affiliate Country Programme (in the case of the IEC), technically you are not allowed to do so. The same applies to regional standardisation bodies that are recognised as such by ISO and IEC. Some sub-regional standardisation bodies do not have this recognition, hence may not adopt ISO or IEC standards either. Most of the other international standardisation bodies are intergovernmental bodies of some sort, and allow the free use of their standards, albeit with certain conditions attached.

national standards, the responsibility for their development and publication, the establishment of the NSB and its governance, funding, responsibilities and activities. Examples of good legislative instruments should be sought from countries that have similar legal systems before developing or revising their own.

2.4.2 Common Challenges in Standards and Technical Regulation

Many developing countries established their NSBs many years ago and have a system for standards development and publication in place. Because such systems work to a certain extent, there is a danger that such countries do recognise that it is necessary to review them. Common challenges in the area of standardisation and technical regulation are the following:

a. Standards development is an expensive and time consuming business as it is based on transparency and consensus principles. Hence national standards should only be developed if there is a real and demonstrable need for doing so and not because it is fashionable to publish specific standards or chase a predetermined number to be published. The NSB should furthermore ensure that the standards development process unequivocally meets all the requirements of Annex 3 of the WTO TBT Agreement.
b. Standards are developed in technical committees. These should be representative of the major stakeholders within a given context. The private sector should play the leading role in such technical committees, as they would be the ones that will have to implement the standards in the first place. Hence, the NSB should not be content with representatives mainly from the public sector, but should vigorously solicit meaningful private sector participation.
c. The NSB or NC should represent the country in regional and international standards development where it matters, i.e. for sectors and issues relevant to the local industry and authorities. In these cases, NSBs or NCs should participate actively in international technical committees, and not only in annual General Assemblies – see Box 3. Mirror technical committees are a very useful method for securing the country position on standards being developed at the regional or international level.

Box 3: Developing countries in ISO technical committees

The five traditional 'standards makers' – Germany, France, Japan, United Kingdom and USA collectively hold more than 60% of the international technical committees secretariats in ISO, in essence managing standardisation at the international level. China is vigorously pursuing the same goal, i.e. garnering technical committees that become vacant or are newly established. At the opposite part of the spectrum, only a few developing countries have strategies in place to make a difference for their industry where it really counts:

- South Africa, as a major coal export country, hosts *ISO/TC 27, Solid mineral fuels*.
- Malaysia, as a major producer of natural rubber and rubber products, hosts *ISO/TC 45, Rubber and rubber products*, as well as *ISO/TC 157, Mechanical contraceptives*.
- India, with its large leather industry, hosts *ISO/TC 120, Leather*.

Source: ISO website: https://www.iso.org/home.html

d. Few countries are 'standards makers', most are 'standards takers'. This is especially the case for developing countries. Developing countries should therefore endeavour to adopt international standards as much as possible, and the NSB should help resist the temptation of local industry or the authorities to utilise national standards as a disguised trade barrier against imported products. The NSB should rather follow a strategy to influence those international standards that are of prime interest to the country by meaningful participation in the relevant international technical committees.
e. Ministries should be encouraged to utilise standards as the basis of their technical regulation, even to the extent that they reference standards in technical regulation instead of detailing technical requirements in full. Furthermore, Ministries should be persuaded not to publish normative documents themselves, but to use the NSB for doing so. The NSB on the other hand should recognise Ministries as SDOs and allow them the final veto on content in cases where specific standards are to become technical regulations.
f. Information on standards and the international and regional standards development processes rely heavily on electronic communication. Hence, robust internet connections are important. Slow and/or intermittent connectivity may lead to an ineffective standards information system and a lack of influence in international standards development.

2.5 Good Practices for Accreditation

2.5.1 National Accreditation Body (NAB)[21]

Primary responsibility

The primary responsibility of the National Accreditation Body (NAB) is to give formal recognition that laboratories of various kinds (e.g. testing, calibration, pathology, etc.), certification bodies, inspection bodies, proficiency scheme providers and good laboratory practice test facilities are competent to carry out specific tasks. The accreditation process is based on international standards such as ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17065 and others. Such accreditation has become a prerequisite for the recognition of results from conformity assessment service providers in technical regulation and in the marketplace at the local and international level.

Organisational form

Theoretically NABs can take on many forms, but due to the fact that NABs are a government instrument in terms of competency recognition, many NABs are either government departments or public institutions. Private NABs are rare, and even those that are set up as private organisations initially in order to speed up their establishment and recognition process are later morphed into public institutions – see Box 4.

There is no international agreement that limits the number of NABs in a country. Hence, due to historical developments, more than one accreditation body was established in some countries. There is however a price to pay for such fragmentation. For example, recognition at the international level has to be sought for each of the accreditation bodies, and overlaps and gaps can create confusion, for instance about which body represents the country at the international level. The trend

[21] The roadmap to an Accreditation System, Physikalisch-Technische Bundesanstalt (PTB).

therefore has been to merge the multiple accreditation bodies into one national body as has been the case recently in a number of European countries such as Germany and Italy.

Another issue that needs to be considered is whether the NAB will be established as an independent, stand-alone organisation, or whether it can be combined successfully with another in the QI. Combinations are possible, and have been successfully practiced in a small number of countries. For example, accreditation and standards have been successfully combined in SCC (Canada), DSM (Malaysia), CYS (Cyprus) and BSN (Indonesia). A caveat is that such organisations can under no circumstances provide conformity assessment services; this would be a clear conflict of interest.

ISO/IEC 17011 specifies the governance structures of an NAB to a large extent. Over and above the Council or Board of Directors, various groups that represent clients have to be established as well as technical committees for each sector to provide the NAB with advice on the accreditation decisions regarding companies that were assessed.

International recognition

The International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) are the international bodies through which international recognition of NABs is accorded. ILAC manages recognition in the field of laboratory and inspection accreditation, and the IAF the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. ILAC and IAF work together and coordinate their efforts to enhance the accreditation and the conformity assessment worldwide. In order to gain such international recognition, the NAB has to demonstrate its own competency vis-à-vis its peers. This is a lengthy process; experience suggests that it takes between five to seven years at least.

Box 4: The stories of SANAS, TUNAC and Viet Nam's Bureau of Accreditation

South Africa: SANAS

Accreditation was started in South Africa by the National Metrology Laboratory of the Council for Scientific and Industrial Research (CSIR) and by the South African Bureau of Standards (SABS). The responsible Ministry, the Department of Trade and Industry (DTI), obtained Cabinet approval in 1994 to establish a single, national accreditation system for South Africa. As an interim measure the National Laboratory Accreditation Service (NLA) was registered as a not-for-profit private company in order to meet international requirements pertaining to independence.

The South African National Accreditation System (SANAS) was registered mid-1995 as a not-for-profit company, and all the activities of the NLA were transferred to it. A Memorandum of Agreement was signed between SANAS and the DTI, through which SANAS was recognised as the single national authority for the accreditation of test and calibration laboratories, inspection bodies, bodies for certification of quality and environmental management systems, and product conformity certification bodies.

SANAS became fully operational during 1998, handling the accreditation of laboratories, inspection bodies and certification bodies. Laboratory accreditation was continued seamlessly from the previous NLA system. SANAS pursued international recognition vigorously, and is a signatory of the Multilateral Recognition Arrangements/Agreements of the IAF since 1998 and of ILAC since 2000.

In the meantime, the government developed the accreditation legislation, resulting in the promulgation of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act 19 of 2006). On 1 May 2007, SANAS became a statutory body under this act, all personnel, assets and liabilities of SANAS as a not-for-profit company were transferred, and it was deregistered. Since its beginning, SANAS has provided accreditation services to South Africa and many others within SADC (it has accredited over 700 organisations) and maintained its international recognition. SANAS and is currently twinning with SADCAS and MAURITAS within SADC to support their quest for international recognition.

Tunisia: Tunisian Accreditation Council (TUNAC)

The Tunisian Accreditation Council (TUNAC) was created by the law no. 70-95 in 1995 and was under the supervision of the Ministry of Industry until October 2005. During this first period more than 200 accreditation evaluators and technical experts were trained and qualified and a pool of testing laboratories and certification bodies were accredited by TUNAC. The accreditation decision was then taken by a Council chaired by the Minister of Industry and composed of representatives of all stakeholders including the private sector and consumer protection associations.

In 2005, TUNAC gained independence under the Law no. 92-2005 and was turned into a non-administrative and non-profit public company. TUNAC benefited from multiple technical cooperation agreements with several international organisations including UNIDO. As a consequence, TUNAC implemented a management organisation in conformity with international good practices of accreditation according the requirements of the standard ISO 17011 and ILAC / IAF guidance.

TUNAC's activities cover all conformity assessment bodies, namely testing and calibration laboratories including biomedical, certification bodies (system, product and competencies) and inspection bodies.

In 2000, TUNAC was accepted as an ILAC/IAF associated member and signed the Mutual Recognition Agreements with ILAC/IAF and EA in 2008. Since then, TUNAC has actively participated in South-South cooperation by participating in the launching of the Arab Accreditation Council (ARAC) and providing technical assistance to some Arab and African Accreditation Bodies.

Vietnam: Bureau of Accreditation (BoA)

Accreditation activities in Vietnam started in 1990 after the issuance of an Ordinance on Product Quality. From 1990 to 1995, 56 different types of laboratories have been accredited against ISO/IEC Guide 25 by the Directorate for Standards and Quality (STAMEQ). By the end of 1995, and to promote international and regional integration on accreditation, the Ministry of Science and Technology (formally named Ministry of Science, Technology and Environment) issued Decision No 1479/QD-TDC on the regulations for certification and accreditation activities. Also in 1995, the Ministry of Science and Technology made a decision to establish the Bureau of Accreditation (BoA) under the Directorate for Standards and Quality. The Bureau of Accreditation is responsible for all accreditation activities in Vietnam, including the accreditation of testing and calibration laboratories, certification bodies, inspection bodies and auditor registration.

The BoA's primary objectives are to contribute to increasing the managerial and technical competence of conformity assessment bodies (CABs) based on international standards and to provide confidence for customers and regulators in the market of the results of accredited CABs. BoA's vision is to be an accreditation body with regional status.

Vietnam has been full member of the International Laboratory Accreditation Cooperation (ILAC) since 1992, a full member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) since 1995 and a full member of the Pacific Accreditation Cooperation (PAC) since 1995. In August 1998, BoA applied to join the APLAC MRA. After assessment, VILAS was approved to sign the APLAC Mutual Recognition Arrangement in October 2000, and the ILAC Mutual Recognition Arrangement in November 2000 in the fields of testing and calibration. Participation in the APLAC MRA and ILAC MRA demonstrates that the VILAS scheme is internationally recognised, and helps underpin Vietnam's trade with the rest of the world. To ensure the accreditation scheme operates objectively and impartially, while also meeting international best practice, BoA developed and implemented a quality system conforming to ISO/IEC Guide 58 and Guide 61, set up Accreditation Technical Committees (TCs) and developed an auditor pool with a hundred trained and experienced experts for BoA's different types of accreditation programmes.

Source: Websites of mentioned institutions, augmented by authors

Industry certification scheme accreditation

Certification has become a multi-billion dollar business. Many industry-based certification schemes have therefore set up their own accreditation systems outside ILAC and IAF. Typical examples include: GlobalGAP certification scheme for food and horticulture products destined for Europe, sub-suppliers to the automotive industry (ISO/TS 16949), various multinational certification schemes such as FairTrade, social accountability (SA 8000), wood products (FSC - Forest Stewardship Council), seafood from renewable sources (MSC - Marine Stewardship Council) and many more. Any developing country where these schemes may be of commercial interest to its industry should contact the relevant parent organisation for details. In some cases, the work of the NAB may be recognised, but in most cases it is not be. In a few cases International recognition frameworks provided by IAF and ILAC are used as part of the industry certification scheme recognition criteria, in the domain of electrotechnical goods, the IEC CA Systems multilateral recognition agreement, based on peer-assessment, is widely used..

Legal arrangements

Accreditation is a tool utilised by governments to denote and publicly communicate competency in the field of technical regulation. It is therefore logical that accreditation should be given legal certainty through appropriate legislative instruments[22]. As a minimum, the legislative instrument should promote accreditation as the primary method of recognising the competence of QI

[22] If a country does not establish its own national accreditation body and makes use of the services of the accreditation body of another country or of a regional accreditation body, it is still good practice to establish legal certainty. The legal instrument to do so would obviously look quite different to one that establishes a national accreditation body.

organisations providing services with a public responsibility (e.g. technical regulation, health and safety, environment), establish the national accreditation body with a legal monopoly, compel all local authorities to recognise it, and provide for its authority, governance, finances and activities.

2.5.2 Common Challenges in Accreditation

Common challenges in the area of accreditation are the following:

- Accreditation is not free, and accredited organisations need to pay the NAB an annual fee over and above the initial accreditation costs. Hence, NABs can in theory become self-sufficient. It has been shown empirically that 200 to 250 accredited organisations are required before this happens. In many smaller developing countries this would be difficult, and financial support from government will be needed for a long time. Even in countries where the NAB has surpassed these figures comfortably, government support may still be provided for the regional and international liaison work of the NAB as a representative of the country.
- A newly established NAB does not automatically gain international recognition. It has to demonstrate its competence to peers by conducting assessments and issuing certificates. Through ILAC and the IAF this can take up to seven years, as experience in NABs has shown. Potential clients, however wish to have an accreditation certificate that enjoys international recognition and may be unwilling to support the new accreditation body. To overcome this challenge, newly established NABs may enter into 'twinning agreements' with an established NAB to can fast-track the recognition process, and at the same time offer clients a certificate that is internationally recognised. Once the new NAB is recognised internationally, the twinning partner will usually withdraw, as accreditation is typically a non-competitive activity as agreed to by the relevant NABs[23].
- Assessments for accreditation have to be conducted by trained and registered assessors. Training of assessors can easily be accommodated during a development programme. However, they have to gain practical experience and hence need to get involved in assessments. These may not be easily organised because of the lack of organisations in the country that are ready for accreditation. There are two ways to deal with this challenge: (i) the development programme may support organisations that wish to become accredited during the life span of the programme, in which case they would be instructed to utilise these assessors under supervision of foreign mentors, or (ii) these auditors will have to be sent to foreign accreditation bodies as interns.

2.6 Good Practices for Conformity Assessment

2.6.1 Institutional Arrangements

Primary responsibility

The conformity assessment service providers are responsible for inspection, testing and certification, i.e. providing evidence that a product, process or service meets stated requirements in a standard or

[23] Although competition between NABs is not specifically prohibited by ILAC and IAF, many have agreed amongst themselves that they will not solicit business in each other's territory. Otherwise the accreditation business would become competitive and subject to market forces that may have a negative influence on the required and perceived objectivity of accreditation.

a technical regulation. Such evidence can be provided by the manufacturer (i.e. the first party), the purchaser (i.e. the second party) or an independent third party. If only the manufacturer or supplier does the inspection and testing[24], the results may not be recognised fully by the purchaser or the regulatory authorities. Testing by the purchaser is an expensive option and not often encountered. Hence an independent third party service provider may be called upon, which is termed certification.

Organisational form

Conformity assessment service providers can come in any organisational form, public or private. There are no fundamental limitations other than the normative requirements in ISO/IEC 17000, e.g. ensuring independence. In developed economies, governments mostly leave conformity assessment to the private sector, whereas in developing economies the state frequently still plays a major role. NSBs and various government laboratories provide the bulk of the conformity assessment services in this case. The international trend however is for governments to withdraw progressively from such service provision as soon as the private sector develops. The strategic challenge is to ensure that no serious gaps develop as the change-over occurs.

International recognition

Recognition by authorities at the local level is provided by accreditation, while within the marketplace at the local and international level recognition can also be achieved by other appropriate conformity assessment methods. There are still cases where regulatory authorities recognise laboratories of their choice on other grounds, but this practice is falling out of favour. In the first place, the technical competency of the conformity assessment service provider has to be demonstrated through independent means (e.g. accreditation); regulatory authorities may then designate conformity assessment service providers, imposing additional requirements that are not covered by accreditation, e.g. legal accountability in the country.

Legal arrangements

Conformity assessment service providers in the public domain would obviously require legislation authorising them to provide specific services. Such legislation should not confer a legal monopoly to such entities – that would constitute an unnecessary barrier to trade and hence a violation of the basic premise of the WTO TBT Agreement.

2.6.2 Common Challenges in Conformity Assessment

Common challenges in the area of conformity assessment are the following;

- It is often considered an asset for every ministry to establish its own laboratories. This leads to duplication of laboratories, puts pressure on the supply of scarce human resources and government finances. In addition, due to the limited amount of testing to be done in the country, most laboratories then operate far below capacity, putting financial sustainability out of reach. The situation is frequently exacerbated by development partners that establish laboratories in different ministries they deal with as partners. It would be far better to conduct a holistic review

[24] The supplier cannot certify by definition – certification can only be provided by the second or third party, usually only the third party. If the manufacturer wishes to provide an attestation of compliance, then we would speak of a 'supplier's declaration of conformity'.

of the capacity available, determine the country's need as a whole, and then make considered decisions regarding the establishment of laboratories, even to the extent of merging existing laboratories.

- Laboratory work is nowadays heavily based on electronic equipment. Development partners often provide such equipment. This equipment has to be serviced and maintained regularly. In developing economies this is a major challenge, and the service usually has to be acquired from abroad at great cost. The situation is exacerbated by development partners that provide many different makes of equipment, instead of standardising on one or two makes that can be serviced simultaneously – even leading to the establishment of an agency by the equipment manufacturer in the developing country.
- Cost is a fact, price is a decision. The cost of testing can be readily determined, but the pricing of services is frequently subject to political control. It is obvious that there is political desire to provide testing services especially to the SME sector at low (i.e. subsidized) price levels. The disadvantage of this practice is that the laboratory or certification organisation cannot attain financial sustainability, whilst the government is unwilling to pay for the difference. This is not a tenable situation. The price for testing should at least cover the real costs plus a reasonable margin in order to plan for future developments and replacement of aging equipment. The QI institution should therefore have the freedom to arrange prices in line with market realities. Support for the SME sector is a laudable endeavour, but should be provided through other means.
- Assessments for certification (e.g. ISO 9000, ISO 14000, etc.) have to be conducted by trained and competent auditors. Training of auditors can easily be implemented during a development programme. If they wish to get registered they have to gain practical experience, and hence need to be involved in audits. This may not be easily arranged because of the lack of organisations in the country that are ready for certification. There are two ways to deal with this challenge: (i) the development programme may support organisations that wish to become certified during the life span of the programme, in which case they would be instructed to utilise these auditors under the supervision of foreign mentors, or (ii) some auditors may have to be sent to foreign certification bodies as interns. The decision as to which to follow will depend on finances, timing and project design decisions.
- A national certification body, if it does not already exist in the NSB, is frequently a wish of governments to support SME sectors, in view of the expensive certification services of multinationals. Before establishing such a national body, the business case should be very clearly defined and articulated. An informed decision has to be made as to whether such a national certification body should be established as a department of the NSB or whether it should operate independently as a public entity or a private company. Establishing such a body will be expensive as it will have to be subsidised for at least three to four years before it will gain self-sufficiency. During this time, policies and procedures have to be developed and fully implemented in compliance with ISO/IEC 17021 (system certification) or ISO/IEC 17065 (product certification), auditors have to be trained, clients have to be sought, and accreditation pursued. Joining

international schemes such as the IEC Conformity Assessment Systems[25] is another consideration. The price of certification should cover all costs plus a reasonable margin to ensure the long-term financial sustainability of such a national body. This body should not provide subsidised services to industry as this would distort the market – any such subsidies should be provided through other channels. This body should at least be able to compete successfully with the multinational certification bodies in the local market.

2.7 Good Practices in Food Safety

2.7.1 Background

Dating from 1995, the SPS Agreement under the WTO requests member states to ensure that food safety (as well as animal and plant health) measures are not applied as an unjustifiable barrier to trade, by requiring that such measures be non-discriminatory (i.e. equally applied to national products and international trade) and that they be based on science (i.e. proportionate to the risk). At the same time, the globalisation of the food industry, advances in processing and distribution technology, and external factors such as climate change and evolving pathogens have an impact on the safety of food. Hence, they represent significant challenges to the regulatory systems that aim to ensure delivery of safe food to consumers. Many countries have found their traditional food safety systems insufficient for this challenge. Especially where food safety responsibilities have been divided between different institutions, the demand for effective coordination of food safety has led to a restructuring of food safety control institutions.

There are a great variety of legal and institutional arrangements for regulation of food safety across countries. In some countries the NSB has been given the responsibility for the administration of mandatory standards for food safety. However, health authorities – as part of their public health mandate – also frequently take responsibility for food hygiene inspections, health of food workers and condition of water supplies, as well as approvals of veterinary medicines for use in food animals. Agriculture authorities may take responsibility for residues of agro-chemicals (pesticides and veterinary medicines) in food stuffs, as well as for zoonoses transmitted by food (often the responsibility of a veterinary department). This may extend to inspection and control of foods of animal origin (meat inspection, dairy and poultry hygiene etc.). Different legal frameworks may be in place for each of these areas. Actual control and inspection at the level of the food enterprise may be a function of regional offices of central government, or may be delegated to local government. It is not atypical for all of these authorities to exist simultaneously. This creates a significant institutional challenge when a response to a food safety issue demands coordinated, and often immediate, action (with budget implications) across ministerial and institutional boundaries.

Development partners that consider supporting food safety elements of the quality infrastructure are therefore encouraged to pay particular attention to the institutional arrangements in place, and

[25] The IEC operates four conformity assessment systems at the international level, namely the IECEE (electrical and electronic equipment), IECEx (explosive atmospheres), IECQ (electronic components) and IECRE (equipment for use in renewable energy applications) systems. Members of these systems will accept test results from members of other countries for the purpose of issuing certificates or even technical regulation approvals. Details can be obtained from the IEC website at https://www.iec.ch/homepage

to ensure that there is a clear definition of mandates. The joint FAO/WHO publication 'Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems'[26], recommends the adoption of either an integrated approach or a single food safety authority. In both cases responsibility for food safety is defined at all levels of the supply chain. In some cases it may be appropriate for donors to apply pre-conditions to an intervention approach, to ensure that the appropriate institutional arrangements are adopted by the beneficiary government.

2.7.2 Institutional Reform for Food Safety

Many countries have opted to restructure their food safety institutions, to ensure clarified mandates. In the integrated approach, food safety responsibilities may be divided between different institutions, with mechanisms for coordination to avoid overlaps or gaps of coverage of controls. To avoid coordination difficulties, a number of countries have opted to establish a single authority to take overall responsibility for food safety. In both cases certain functions may be delegated to other relevant bodies, including local inspection authorities. Food safety authorities may not only deal with sanitary measures, but in some cases are responsible for animal health and phytosanitary issues as well.

The development of such authorities requires care to avoid overlap and duplication, to ensure that new mandates are properly defined and existing mandates revised, especially in cases where existing institutions have been responsible for certain aspects of food safety and quality. Such authorities are often established via a food safety law, which also defines the modern principles of food safety (in line with the SPS Agreement) as well as adjusting the historical mandates of existing institutions. Two important areas to address are the relationships between the food safety authority and testing laboratories on the one hand, and National Standards Bodies on the other.

2.7.3 Role of the National Standards Body

In some countries the NSB, for historical reasons, may have published national standards for food items which then have been declared mandatory by the parent Ministry (often concerned with trade, commerce and industry). This situation could lead to potential confrontation between the NSB and food safety institutions, and their parent Ministries, and is often exacerbated by the fact that the NSB may obtain a significant percentage of its income from the mandatory certification of food items (i.e. sampling and testing for compliance with standards). Mandatory certification is a model proven to be ineffective for the control of food safety.

Where development partners support the restructuring of the food safety control system it is extremely important that they are aware of these issues. They should ensure that the programme design facilitates dialogue between the parent Ministries, enables the smooth transfer of administrative responsibility, and creates a clear set of mandates. In general, the NSB should publish only voluntary standards for food products. These may include food safety criteria, as well as non-safety criteria (such as commercial quality).

[26] 'Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems', Joint FAO/WHO Publication, FAO Food and Nutrition Paper No.76, ISSN 0254 4725.

The food safety authority, as the risk management body, may choose to manage a food safety risk by regulation (it may also choose other tools such as public information). In this case it may adopt a published standard, in full or in part, as it sees fit to meet the needs for effective control. It is important to ensure that the system does not permit differences in food safety criteria between the voluntary standard and the technical regulation. Where a regulator deems it necessary to set a different requirement (for example, where the country wishes to set a food safety measure at variance with Codex Alimentarius, as a result of risk assessment), then the voluntary standard should be amended.

2.7.4 Role of Testing Laboratories

Development partners wishing to help strengthen food safety controls have long supported the strengthening of laboratory testing capacity, for example: Construction of laboratories, supply of analytical equipment, and training of staff in techniques, accreditation and quality assurance. These efforts need to be accompanied by parallel support to strengthen governance of the control system in order to be successful in the long-term.

Some issues, however, need to be taken into account. It is not essential for the control authority to own or operate a laboratory. Laboratories provide a service which may be provided by any competent provider. Before a decision is made to invest in public sector laboratory capacity it is necessary to carefully consider whether such tests could be more economically sourced externally, including overseas (classic 'make or buy' decisions). Secondly, it is important to recognise that measurement is not control. Safe food is best created by operators' use of safe practices in the supply chain; this should ideally only be complemented by the gate-keeping process of testing/rejection at the point of consignment to market.

In particular when testing/rejection models of control are applied in export certification, non-compliant products are simply re-directed to less stringent markets (resulting in unsafe or uncontrolled foods being consumed within the country or region, without addressing the factors giving rise to the non-compliance). This can be avoided through the strengthening of the control system along the supply chain.

2.7.5 Food Safety Policy

Development of a coherent food safety policy serves several objectives:

- Firstly, and most importantly, it provides for improved public health through the provision of safe food. As such, food safety is often regarded as an integral element of a country's food security policy. Food must not only be sufficient to meet nutritional needs; it is also a *sine qua non* that it should not harm the consumer. The country thus reduces the costs of health care and loss of economic benefits due to illness and premature death.
- Secondly, regulatory measures for food safety ensure that agricultural and food production systems meet minimum standards of safety in export markets, thus providing benefits for international trade by ensuring that products obtain and keep access to international markets, and do not suffer rejections and price discounts associated with the loss of buyer confidence.
- Thirdly, food safety policy addresses the agro-food business investment climate by eliminating (through regulatory measures) non-compliant operators from the supply chain. It provides a

guarantee to investors in improved production systems that they will not be undercut by lower cost operators who do not comply with the requirements for food safety and quality. In this way, food safety policy can therefore contribute significantly to improved competitiveness in the agricultural and food sector.

Food safety policy should clearly define institutional responsibilities, as set out above. It should recognise that food safety is essentially a process of risk management (not every item of food can be checked to see if it is safe). There are many specific functions which need to be coordinated to ensure that a modern and effective food safety system functions as a whole, to identify and assess risks, and to manage and communicate those risks. At the minimum, a risk-based approach which complies with the SPS Agreement will need to address these three functions of risk assessment, risk management and risk communication. Risk assessment will require the development of a system of scientific advice to risk managers. Risk management requires authorities to make a judgment regarding the optimal (in terms of costs and benefits) control strategy.

Regulatory controls invariably impact on costs sustained by food production businesses, and need to be applied in consultation with stakeholders (requiring policy to reflect on how such views are to be solicited and taken into account). All public officials involved in regulatory enforcement are subject to extra-professional influences on their decisions, such as corruption. Often, however, these influences occur (and especially in countries with weak governance) in the form of peer group pressures. It is good practice for policy to recognise such pressures and seek to protect officials from their influence.

2.8 Good Practices in Private Standards[27]

2.8.1 Origin of Private Standards

Increasingly, standards are developed outside the auspices of national, regional, and international standards bodies. The development of these private standards has clear causes, for example:

- Consumers, as well as civil society organisations in developed economies, have growing concerns about the social and environmental conditions prevailing in countries that participate in the supply chains of products that are sold into their markets. As cases of severe breaches of workers' rights, occupational safety risks, human rights violations and environmental degradation caused by corporate activity reach the public, consumer confidence in the conduct of the major brands and retailers decreases. Consequently, globally operating companies find themselves faced with the challenge of responding to these consumer concerns.
- Suppliers work together to gain market advantages in supplying products with similar technology. For instance, the CD system standard specifications were produced jointly by Philips-Sony, and the GSM standards (Global System for Mobile Communications) for mobile phones were agreed to by a few manufacturers.

Private standards are developed by sectoral organisations including non-governmental organisations, consortia, certification bodies or major retailers. Private standards are generally geared to meet the needs of those who develop and publish them and are not intended for mandatory application by the

[27] Making Private Standards work for you, UNIDO.

government. Private standards usually require certification, because a supplier's declaration of conformity is not accepted. Hence the decision by a supplier to obtain certification against a private standard is always a business decision, depending on whether it will be profitable to do so.

2.8.2 Typical Private Standards relevant to Trade

Typical private standards that are relevant for producers in developing economies include GlobalGAP (food and horticulture products destined for Europe), FSC (wood, paper and pulp products from renewable forestry operations), FairTrade (ethical trade), SA 8000 (social accountability) and many more. Information on these standards is fairly easy to obtain through the internet as these organisations wish to publicise their services as much as possible.

2.8.3 Common Challenges

Some of the challenges emanating from the market relevance of private standards are as follows:

- Providing technical assistance in the private standard domain should be considered carefully by the development partner. Such technical assistance frequently supports the business activities of one private service provider to the detriment of others. In addition, helping a supplier (i.e. a SME) to gain the required certification may lock the supplier into the supply chain of a single major purchaser such as a multinational retail chain, making it very difficult to trade with others. Such a decision therefore has to resonate with the strategies and policies of the development partner, but also with those of the recipient country.
- Certification can frequently only be obtained through a foreign certification body and not automatically through the NSB. This is an expensive operation, and hence every effort should be made to obtain recognition of NSB certification activities through the parent organisation of the private standard certification body.
- Private standards are revised fairly frequently, as major retailers respond rapidly to shifting consumer demands and try to maintain a market advantage over rivals. This means that suppliers have to respond equally rapidly in updating their systems, otherwise they lose their certification. Development projects supporting suppliers need to be aware of such developments.
- Private standards are frequently utilised by major retailers to differentiate themselves from rivals. Hence certification to one private standard is not readily transferable to the next. This is a particular challenge for SMEs that can ill afford to maintain a multiplicity of certifications. The choice of which private standard(s) to be certified against therefore has to be taken with great care.
- Private standards are not always well received by the public standards organisations[28]. This can lead to unnecessary confrontations or silent sabotage amongst the NSB and representatives of such certification schemes. Every effort should be made to facilitate dialogue, as both public and private standards are a market reality in the developed economies that are the focus of exports from developing countries.

[28] International standards and 'private standards', ISO.

3 Good Practices of Quality Infrastructure Development at Regional Level

Regional economic integration can come in a number of forms: (i) Preferred Trade Area, (ii) Free Trade Area, (iii) Customs Union, (iv) Common Market, or (v) Economic Union. These forms do not represent stages in the sense of a linear progression, and each can be introduced in its own right. Of these, Free Trade Areas absolutely dominate the more than 150 existing Regional Trade Agreements (RTAs) notified to the WTO. Free Trade Areas are agreements on the extensive reduction of trade restrictions between member states, usually covering the overall trade in goods; standards and/or technical regulation issues are frequently found to be at the centre of these trade restrictions.

Due to this relevance of standards and technical regulation, the issue of QI is a central part of most RTAs. The relevance of the QI is not restricted to trade, but also includes other areas with a high degree of standardisation and quality control activities, such as environmental, health and consumer protection. The importance of the QI and the demands made on its effectiveness grow with the degree of integration: Whereas in relatively flat forms of regional integration overcoming barriers to trade in selected product sectors is important, more pronounced regional integration such as Common Market demands extensive harmonisation in nearly all industrial sectors and the creation of a uniform socio-economic framework.

It is therefore clear that technical assistance in most of its forms has to take the regional context into consideration, even to the extent that regional issues dominate than national ones. National QI issues have been extensively discussed in Section 2 – this section will focus on strengthening QI capacities in regional context.

Technical assistance to the national QI and regional QI are not separate issues, but must always be integrated in a holistic approach depending on the regional context of the developing countries that are to be assisted.

3.1 The Regional Quality Infrastructure Landscape

The effectiveness of the overall QI system will depend on how opportunities and challenges that ensue from the process of regional integration are handled. Opportunities include the utilisation of potentials for regional cooperation and division of labour, e.g. pooling laboratory capacities, exchanging expert knowledge. Challenges include the increased coordination effort and the increased pressure on national systems to harmonise standards and regulatory practices, e.g. setting and implementing common technical regulations and relinquishing their own way of doing (see Box 5). The quality of 'institutions' in the sense of rules, enforcement mechanisms, and organisations therefore plays an essential role in determining the effectiveness of the overall QI system[29]. The regional landscape of QI 'institutions' is shown in Figure 10.

[29] Building institutions for market, World Bank.

Box 5: The West Africa Quality Programme (WAQP)

The Economic Community of West African States (ECOWAS) consists of 15 member states, and includes Benin, Burkina Faso, Cape Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone and Togo. The eight essentially Francophone countries form a subgroup, the West African Economic and Monetary Union (UEMOA) with a common currency, whereas the seven Anglophone countries that make up the rest of ECOWAS do not have a separate construct other than belonging to ECOWAS. The UEMOA countries have long embarked on establishing a regional quality infrastructure, whereas the rest have not. UNIDO initially managed a development programme in UEMOA funded by the EU that lasted from 2001 to 2005. The subsequent West African Quality Programme (WAQP), also funded by the EU, consisted of a 1st phase lasting from 2007-2011, and a transition phase in 2012 in anticipation of a future programme.

The overall objective of the WAQP was to strengthen regional economic integration and trade by creating an environment that facilitated compliance with international trade rules and technical regulations. Of particular importance were the World Trade Organisation (WTO) Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phyto-sanitary Measures (SPS). The overall objective was considered to have been achieved by just over 80% in the final analysis.

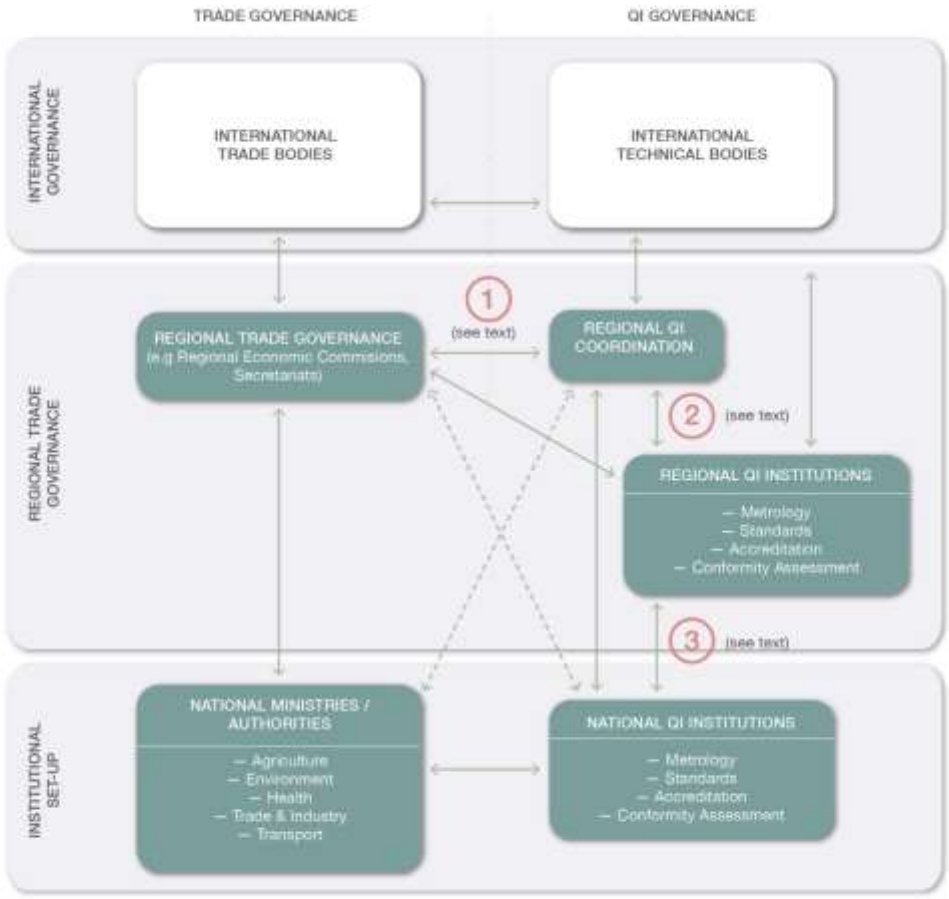
Due to a number of factors, the 1st phase of the WAQP was managed in two distinct, parallel parts. Language no doubt played a role, but more importantly, UEMOA member states had already established regional quality infrastructure constructs that were missing in the others. The main idea behind this duality was to provide space for the Anglophone countries to catch up with the Francophone countries. This had some advantages, namely that each part of the programme could be streamlined to support capacity building at national level in countries with specific needs. This part of the programme was not controversial and hence quite successful. A number of laboratories were upgraded and accredited, and laboratory and auditing staff appropriately trained. National Quality Policies were developed in about half the countries, and advocacy for quality was embarked upon to build a bridge between the public and private sectors.

The major challenge, however, was that the duality of the programme appreciably slowed down the process of integration at the level of the whole of the region, which was the initial goal. Firstly, the programme was caught between two distinct regional governance structures that were themselves in the process of integration, with all the difficulties that accompany such a process. Secondly, whereas UEMOA was very much in favour of regional quality infrastructure organisations (e.g. NORMCERQ for standards, SOAMET for metrology and SOAC for accreditation which it had established and wished to operationalise as much as possible), the larger ECOWAS environment was not. In particular, the two economic powerhouses of the region with well-established national systems, namely Ghana and Nigeria, found it difficult to integrate into a regional system which they had played no part in establishing. Major changes would have to be effected on both sides before this would even be contemplated.

After many months of difficult negotiations, a draft regional quality policy was developed and validated by experts from all the ECOWAS countries during the transition phase of the programme in 2011/2012. In addition, a report defining the future system of the regional quality infrastructure (incorporating both the UEMOA structures and the greater ECOWAS needs and wishes) in terms of its creation, organisation and functioning was validated by experts from all the ECOWAS countries. At the end of the project, both of these still were to be adopted or endorsed by the political levels at the ECOWAS and UEMOA Commissions. Implementing them would be the next major challenges of the region in the quality infrastructure and technical regulation regime domain.

Source: UNIDO in ITC International Trade Forum Magazine and Final Programme Evaluation Report

Figure 11: Quality Infrastructure governance, coordination and institutional set-up at national, regional and international level



Source: Adapted from "Contribution of quality infrastructure to regional economic integration", PTB

Three distinct but inter-linked areas to regional technical assistance present themselves (as indicated in Figure 9), namely:

Area 1: Governance: Technical assistance regarding the harmonisation of standards and technical regulations at regional level as well as the basic issues of mutual recognition of conformity assessment results and market access.

Area 2: Technical specialist structures: Technical assistance in strengthening regional technical specialist structures to fulfil their mandate to coordinate and harmonise QI activities across the region, with particular consideration of the needs of less developed countries.

Area 3: Regional QI institutions: Technical assistance for the establishment, capacity development and promotion of regional QI organisations that can meet the national and regional demand for quality-related services.

Whichever area is considered for technical assistance, prerequisites for establishing a proper regional technical assistance approach for developing economies include the following[30]:

1. Negotiations on regional technical assistance should not be conducted in isolation from global developments towards harmonisation and mutual recognition;
2. Regional technical assistance should be based on the needs of member states but also in line with the general goals of integration of the region;
3. All efforts should be based on the clear political commitment towards trade liberalization and economic integration; and
4. Resources should be available that specifically aim at the support of developing countries, if possible, as part of integrated economic promotion programmes.

These requirements imply that effective regional QI structures should function in line with international good practices, be based on active participation of relevant stakeholders, and provide for effective communication between decision makers, QI institutions and interested parties.

3.2 Area 1: Technical Assistance within the Scope of Quality Infrastructure Governance

Governance can generally be defined as the rule of rulers. In the context of regional integration and QI in particular, these rules include the strategies, regulations and political decisions that pertain to the intra-regional exchange of goods, including the establishment of the corresponding infrastructure to facilitate the same. The effects of technical assistance for QI governance (see Area 1 in Figure 9) at regional level could be divided into two main categories, namely:

a. Removal of policy asymmetries by coordination and harmonisation of QI related rules and regulation, for example: (i) Preparation of regional guidelines, legislative instruments and information procedures in the area of standards, metrology, accreditation and their application in conformity assessment for technical regulation and the marketplace, (ii) Determination of product areas that are to be harmonised on a regional basis, including the selection of the appropriate harmonisation concepts, and (iii) Definition for the mutual recognition of conformity assessment through regional recognition arrangements or other means with similar outcomes.
b. Removal of structural asymmetries by granting one-sided preferences to less developed countries, for example: (i) Adoption of action plans to upgrade the QI institutions in selected member states, (ii) Arrangement for a regional division of labour, (iii) Facilitation of technical know-how by establishing regional working groups and information platforms, and (iv) Inclusion of recognised national QI institutions in the region in technical cooperation activities.

While in category (a) above, technical assistance is provided at the level of the regional structures, in category (b) it operates mostly at the national level (discussed in detail in Section 2), although preferably with a full understanding and support of the relevant regional structures. Hence, a decision on the appropriate level of technical assistance should be made jointly with relevant regional administrative and/or technical committees as fora for interstate dialogue and exchange of information.

[30] Contribution of quality infrastructure to regional economic integration, PTB.

3.3 Area 2: Technical Assistance to Regional Specialist Technical Structures

3.3.1 General

The specialist technical structures take on many forms depending on the way in which regional institutions are established through the founding agreements of the region. Some are permanent structures at the regional secretariat whereas others are permanent high level committees with specific mandates and defined membership. These are structures that mostly take their cue from the international specialist technical organisations such as ISO and IEC in the standards domain, ILAC and IAF in accreditation, BIPM and OIML in metrology, etc. (see Figures 9 and 10). They are mostly charged with the responsibility to harmonise efforts to facilitate intra-regional trade and ensure the health and safety of humans and the environment at the regional level in the face of relaxed trade regimes.

While in many regions these specialist technical QI structures already exist, in others they may be in need of re-structuring or need to be established. Hence, due to the complexity of the political dynamics and regional structures, the design and management of technical assistance at the regional level is significantly more complex than at the national level. This reality should never be underestimated in project design and planning (see also Box 3). Technical assistance will vary depending on the needs of the region, but could include: (i) Developing or strengthening relevant legal instruments, (ii) building administrative capability, (iii) supporting advocacy to higher levels and/or industry and society at large, (iv) enhancing capacity and capability to manage coordination and harmonisation programmes, etc.

3.3.2 Standards, Metrology and Accreditation

Over time a large number of regional QI organisations and associations have been established, with typical examples such as:
Metrology: AFRIMETS, APMP, COOMET, EUROMET, SIM, etc;
Standards: AIDMO, AFSEC, ARSO, CEN, CENELEC, COPANT, PASC, etc;
Accreditation: AFRAC, APLAC/PAC, EA, IAAC, etc.

A number of sub-regional organisations also exist within trading blocs such as the ASEAN Consultative Committee for Standards and Quality (ACCSQ), the CARICOM Regional Organisation for Standards and Quality (CROSQ), the EAC East Africa Standards Committee, the Gulf Standardisation Organisation for GCC Arab Countries, MERCOSUR Standardisation Association (AMN) and SADC (SADCSTAN, SADCMET, SADCMEL and SADCA).

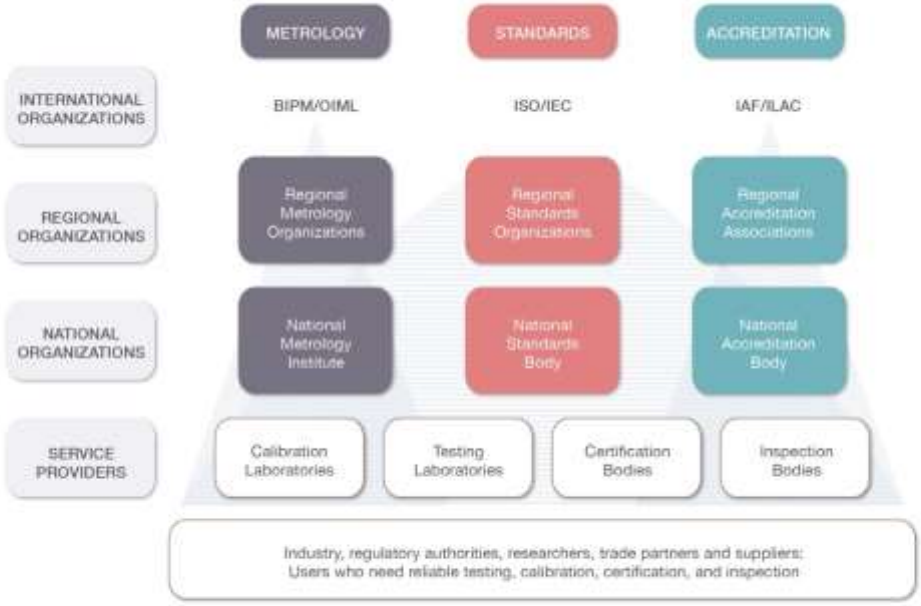
Regional specialist technical structures are probably the most visible expression of transnational cooperation within QI. This applies in particular to the fundamentals, namely metrology, standards and accreditation. Here, the national, regional and international structures are integrated into a system of mutual cooperation and recognition – see Figure 11.

ISO for example, cooperates formally with 10 recognised regional standards organisations and these act as mediators between the national and international levels, having committed themselves to

facilitating the adoption of ISO Standards by their national members as widely as possible. IEC has signed formal cooperation agreements with 8 regional standards organisations in its field.

The role of the regional structures within metrology and accreditation is especially pronounced. The NMIs and NABs – the technical backbone of competence evaluation and traceability of laboratories and certification bodies – depend to a very large extent on formalised cooperation and recognition arrangements at the regional level[31]. The regional organisations on the other hand, are linked to the international organisations via a system of membership culminating in recognition if certain conditions are fulfilled. The important role that regional organisations play in the recognition of national metrology and accreditation systems at the international level is detailed in section 3.4 below.

Figure 12: Structure of national, regional and international Quality Infrastructure organisations



Source: Adapted from World Bank

The relevance of the regional bodies in technical assistance programmes must be taken into consideration, as they are frequently responsible for:

- Managing intra-regional evaluations and comparisons that lead to international recognition of the national bodies;
- Collecting regional know-how and acting as representatives towards other regional organisations and international committees;

[31] IAF ML 4:2012, Policies and procedures for a multilateral recognition arrangement on the level of single accreditation bodies and on the level of regional groups, International Accreditation Forum.

- Establishing the regional framework for exchange of experience, information and scientific cooperation including regional training courses; and
- Building trust among member states through mutual assessments and enhanced personal relations, especially amongst smaller states that work in greater isolation due to lack of resources.

Involving regional specialist organisations in technical assistance programmes is not without challenges. Apart from the fact that some developing countries still have no proper regional representation, the effectiveness of sector networks differs considerably, depending on the level of organisational sophistication and the membership structure. These challenges are compounded due to the fact that many of the smaller developing countries do not participate effectively in regional activities, because to financial and resource person constraints. In addition, many specialist regional organisations feel obliged to treat all members equally instead of taking the direct sponsoring of weaker members sufficiently into consideration.

3.3.3 Regional Food Safety Iinstitutions

Whilst it is recognised that most food safety functions are essentially the responsibility of nation states, there are a number of specific circumstances where it is sensible to pursue a regional institutional approach.

Countries within a region often share the biosphere from which their food is produced, as well as culturally determined methods of handling, processing and consumption. They therefore often face similar food safety challenges. Examples might be the development of aflatoxin in grain crops, or the presence of carcinogenic compounds in smoked and dried fish. Ensuring a harmonised regional approach to the way in which these challenges are addressed can bring benefits for the facilitation of regional trade and sharing and adoption of best practices.

In addition, all WTO members have an interest in ensuring that products specific to their country or region are not excluded from international trade based on standards set by the Codex Alimentarius Commission. Codex standards are elevated to a unique status by the SPS Agreement, under which states are obliged to refer to the internationally mandated organisations (Codex in the case of standards for food safety) in the case that there is a dispute regarding the application of an SPS measure. Clearly, where a group of states within a region share products, processes and food safety challenges, there is an advantage in deciding a common regional position on draft Codex standards, to ensure that the interests of the region as a whole are represented in the final standard.

In general, less developed countries have not been very effective in representing their SPS interests in the process of setting international standards. This process requires effective coordination and communication between sector stakeholders, trade and sanitary policy, as well as between the relevant authorities of the different states with common interests within a region. For this reason, the establishment of SPS functions attached to the regional economic organisations or communities (such as the ECOWAS or SADC in Africa, or ASEAN in Asia) can help ensuring that SPS barriers impact as little as possible on regular trade in agro-food products from less developed countries. Development partners are therefore recommended to support beneficiaries in establishing regional

networks and building the capacity to effectively participate in the setting of international standards in which they have a strategic interest.

Another area with significant scope for regional cooperation is risk assessment. WTO members are allowed to adjust the application of SPS standards set by the internationally mandated bodies where this can be scientifically justified by risk assessment. This a scientific process, defined by Codex, consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterisation. As such, the risk assessment process is underpinned by research into the presence of different hazards, impacts on health, epidemiological studies and food processing technology. Where there are common production and consumption characteristics, collaborative risk assessment for food safety is more cost-effective. Until now, there have been few efforts in less developed countries to establish the regional networks and collaboration required for risk assessment. This may be a useful area for future development support.

Box 6: SPS Harmonisation in the East African Community (EAC)

The member countries of the East African Community (EAC), Kenya, Uganda, Tanzania, Rwanda and Burundi, have the potential to enhance the benefits of their regional trade. To realize this potential, the EAC is working to have tariffs reduced and improve transport and customs logistics. Standards also need to be harmonised and common conformity assessment procedures agreed.

The region is endowed with good agricultural land, and trade in agro-based products can provide an immediate boost to regional trade. It is however critical that standards be harmonised and conformity assessment procedures established in this sector. To assist the EAC in overcoming these challenges, a UNIDO project funded by the Norwegian Agency for Development Cooperation (Norad) established a coordinated national and regional mechanism that facilitates both inter- and intra-regional trade in selected strategic food products, such as fruit and vegetables, coffee and tea, and fish.

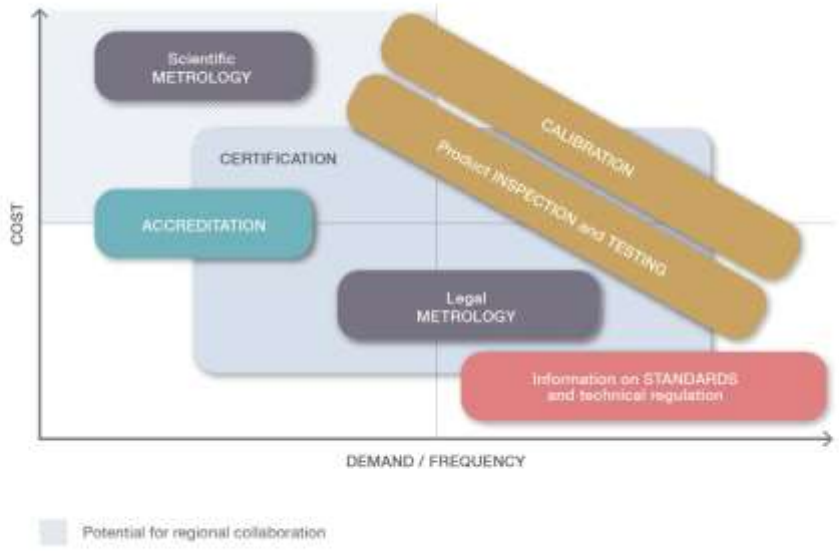
At regional level, the SPS Protocol has been drafted with project support. Harmonised trade related SPS measures have been prepared covering animal and plant health and form annexes to the SPS Protocol. Harmonised trade related food safety standards have also been set as an annex. The SPS Protocol puts in place the regional infrastructure that will enhance the efforts of the EAC Secretariat to promote regional harmonisation of SPS measures and food safety standards in accordance with EAC's regional integration goals to promote intra EAC trade. As the SPS measures and food safety standards are also harmonised with international standards it will also facilitate EAC trade within the WTO multilateral trading system.

Source: UNIDO, Final Programme Evaluation Report EAC

3.4 Area 3: Approaches in Establishing Regional Quality Infrastructure Institutions

The establishment of fully-fledged national QI institutions requires considerable investment and ties up resources on a long-term basis. For many countries with limited financial means and a relatively modest demand for quality-related services this is neither feasible nor useful. Instead, the common use of a regional service provider or a more intense exchange of expertise may be the better approach. As an initial estimation as to what extent QI capacities could be established at a national or a regional level, it is useful to consider a clustering of QI services in terms of the criteria 'cost' and 'demand or frequency' as shown in Figure 12.

Figure 13: Clustering of Quality Infrastructure services



Source: Contribution of quality infrastructure to regional economic integration, PTB

Figure 12 provides a broad picture of the QI services landscape in a region with the cost of typical services on the vertical axis and the demand or frequency for such services on the horizontal axis. Smaller countries of the region may decide that the higher costs of establishing services such as scientific metrology is beyond their resource capabilities, in which case a regional structure would make sense. On the other hand, even a costly service such as calibration, due to the frequent uptake of such services, may warrant the cost of establishing such a service at the national level.

Hence, Figure 12 indicates that even the smallest state should establish legal metrology and information services. For the implementation of legal metrology measures, a local presence is important; it can hardly be done from afar. This is also an area where the positive impact of even rudimentary (i.e. cost-effective) measures will rapidly be felt in the local markets. A well-designed standards information system will connect the country with international systems, thereby providing local industry and authorities with vital information on international standards and technical regulation information.

System certification is an area that shows a wide spread of cost versus demand or frequency. Establishing certification services such as GlobalGAP, FCC or ISO/TR are expensive, and the demand may not be that high at national level – hence a regional approach may be indicated. On the other hand, ISO 9000 type certification would be of great benefit to the SME sector, and establishing a local certification service would better serve this important sector due to lower costs, language issues and greater knowledge regarding local conditions.

The areas of product testing and calibration contain a wide range of possible services that prevent a clear allocation, but inspection and testing for technical regulations (i.e. high demand) may have to

be provided for at the national level. High-end calibration and accreditation on the other hand are low demand or frequency and high cost services that are prime candidates for a regional approach. Before coming to a conclusion for a specific region, real data should be factored into the evaluation.

Cost and demand or frequency are not the only aspects to be considered in making a decision on whether to establish regional or national service delivery organisations or to establish so-called regional centres of excellence to provide high-level technical support to the region. Other aspects that could play a role include the proximity of the service delivery to where it is needed, strategic interests, financial sustainability, availability of technical expertise, transport logistics and rapid customs clearance for test sample movements and national sensitivities. The latter should not be dismissed – it may be that they are important to the recipient countries. A proper business case should be developed that carefully considers all of these before any regional organisation is established.

3.4.1 Regional Metrology

The metrology infrastructure at national level essentially consists of a hierarchy of three levels. The 1st level is occupied by the National Metrology Institute (see 2.2.1), the 2nd level is formed by calibration laboratories (see 3.2.3) which in turn provide calibration services to the 3rd level, test laboratories, industry and the like. Legal metrology occupies positions in both the 2nd and 3rd levels. While legal metrology requires a fundamental metrology infrastructure regarding mass, temperature, volume and length on a national basis, there is potential for regional cooperation in the field of international traceability, establishment of specialised calibration laboratories and training and consultancy. The entry points for regional collaboration in the field of metrology are shown diagrammatically in Figure 13 and are discussed below.

1. Connecting national metrology institutes with the international system of units

Periodic comparison/calibration of national measurement standards is essential for the acceptance of services offered by the NMI. The establishment of primary standards and their calibration is often too challenging for smaller developing countries. A useful option would be the collaboration with a NMI in the region that has international recognition through the participation in CIPM-MRA, i.e. the national standards of the smaller developing country would be calibrated by the latter NMI, thereby ensuring traceability to international standards – see Box 6. A good practice is to facilitate this cooperation through a long-term service contract which could also include training and consultancy services.

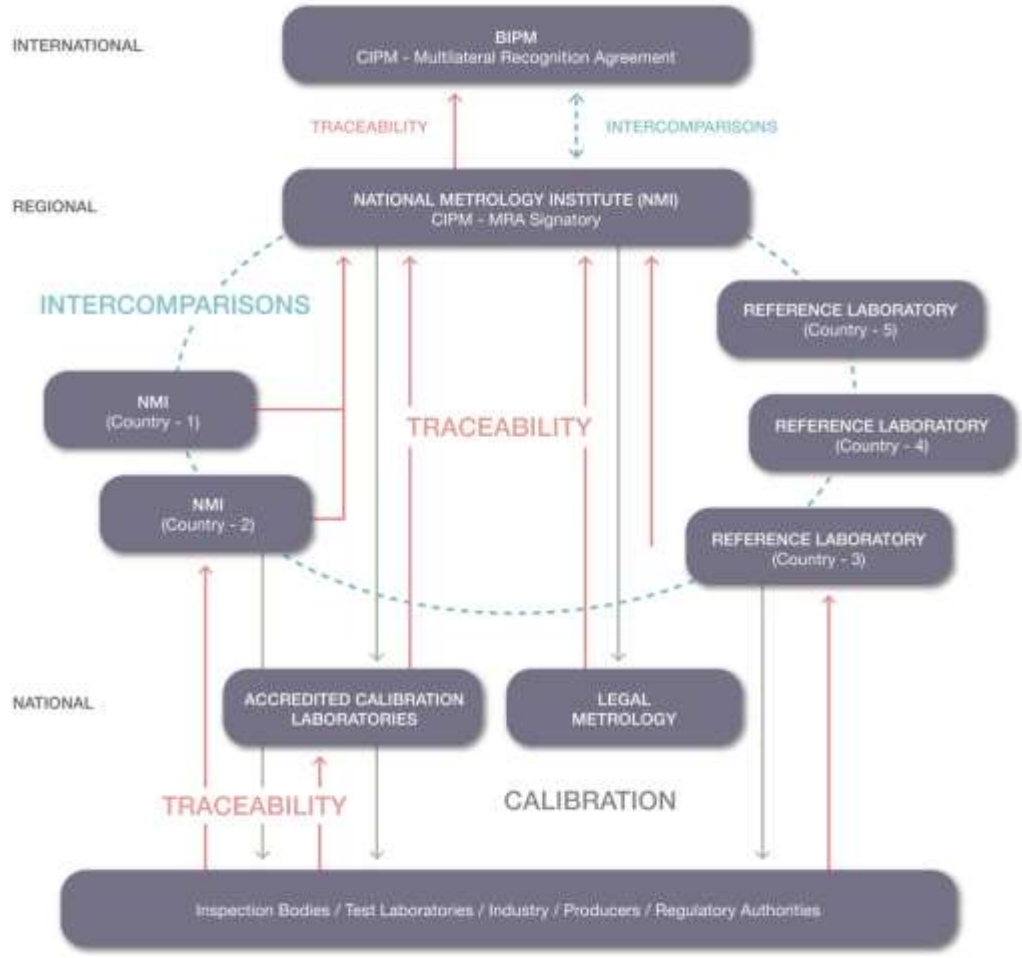
Beyond this, regional inter-comparisons managed by the regional metrology organisations under the auspices of the BIPM have become an indispensable mechanism for the establishment of the CMCs of the member countries. This is due to the sheer volume and hence impossible logistics of running inter-comparisons only at the international level. This is shown graphically in Figure 11 as well. Without such regional inter-comparisons, an international system would not be possible.

2. Establishing a network of reference metrology laboratories

The demand for calibration services depends on the industrial base as well as on the legal metrology requirements. In smaller developing countries, both often fall short of justifying investments in a

purely national calibration infrastructure. The NMI may assume a double function, i.e. acting as a calibration laboratory and ensuring international traceability. But even this may be too much in specialised metrology areas. Hence good practice is to establish a network of reference metrology laboratories in the region that can provide technically competent services in this regard to all member states. The prerequisite for such an approach would be the political support for this division of labour that goes beyond national self-interest – see Box 7.

Figure 14: Regional cooperation in metrology



Source: UNIDO

Box 7: NMI of India and SAARC

The National Physical Laboratory of India (NPLI) occupies a leading position in SAARC. The NPLI is one of the few NMIs in developing countries that has signed the CIPM-MRA and that can guarantee traceability to the international system in numerous measurement fields. In contract, the NMIs of the bordering states, among them smaller developing countries such as Afghanistan, Bangladesh, Bhutan, Maldives and Nepal are mostly in the initial development stage and require technical support in various ways. NPLI ensured the traceability of basic measurement standards under preferential conditions in these countries. Furthermore, regional inter-comparison measurements, for which the NPLI acts as pilot laboratory, were organised within the scope of collaboration within the SAARC Secretariat and development partners. Complimentary training and consultancy support missions of NPLI facilitated the effectiveness of these measures. This cooperation facilitated the international traceability of key measurement standards in neighbouring SAARC countries at a nominal cost.
Source: Contribution of quality infrastructure to regional economic integration, PTB

Box 8: Regional metrology reference laboratories in UEMOA

In most of the countries of the West African Monetary Union (UEMOA) there is a very low demand for industrial metrology and testing. Industrial metrology services were mostly met by European calibration laboratories, whereas the NMIs of the countries had largely limited themselves to legal metrology. The establishment of a regional network of metrology reference laboratories was initiated by the UEMOA Secretariat in Burkina Faso in 2006. After an initial planning and bidding phase, four reference laboratories were identified in four countries for the basic measurement fields of mass, temperature, volume and pressure. They were supported through consultancy services, training on-site in Europe and the supply of measuring equipment, and were assisted to become accredited service providers for the whole region.
Source: Contribution of quality infrastructure to regional economic integration, PTB

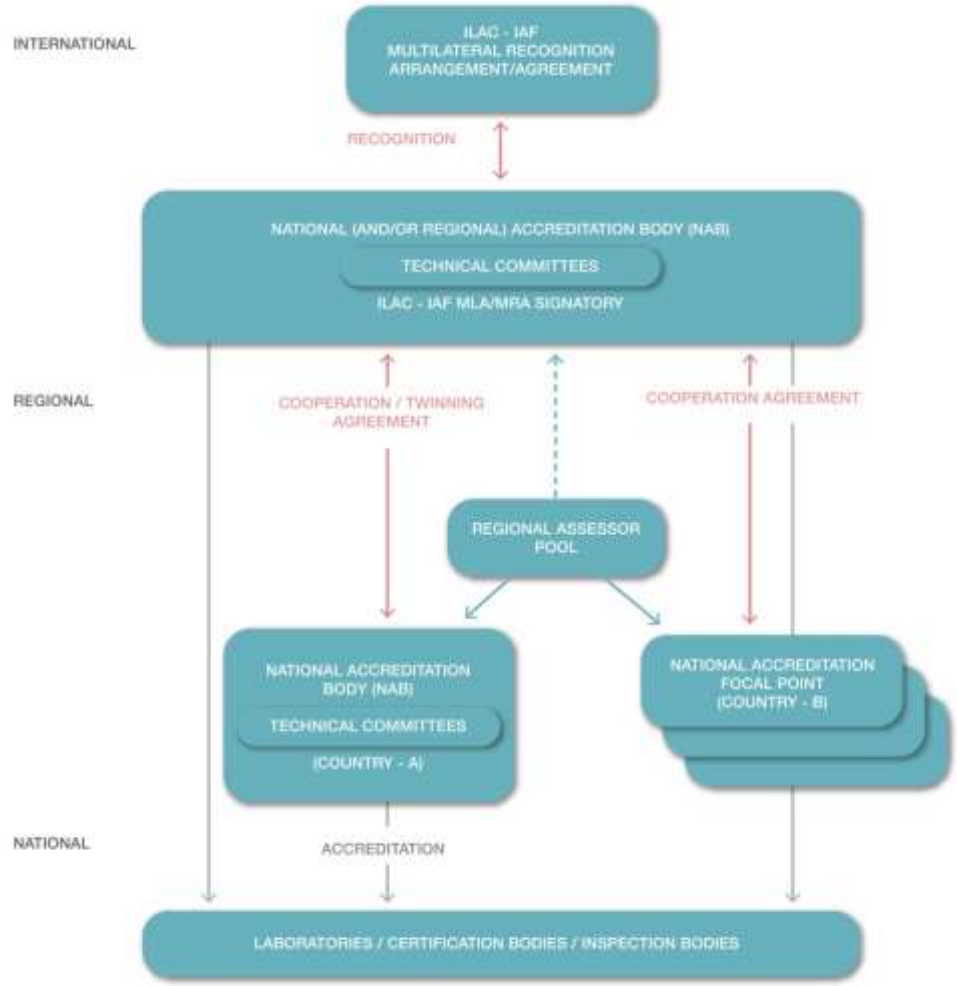
3.4.2 Regional Accreditation

The establishment of a national accreditation body is a worthwhile endeavour (see 3.1.2 and 3.3.3), but a very challenging goal in smaller developing countries: (i) A lack of income from accreditation work means the financing has to be secured from government, putting a strain on independence and financial sustainability, (ii) It is difficult for experts in small countries to gain and maintain the required expertise and competence to stay neutral towards customers, market competitors and regulating authorities, and (iii) The decisive element of accreditation, namely confidence in the certificates issued, can be quickly destroyed by political influence and corruption. On the other hand, the issue of increased costs arising from travel and hotels should not be underestimated.

Opportunities for regional cooperation in accreditation do exist (see Figure 14), for example:

1. Establishment of an office that serves as a national focal point and supports the administrative processing of applications for accreditation in conjunction with a recognised accreditation body of a neighbouring country.

Figure 15: Regional cooperation in accreditation



Source: UNIDO

2. Establishment of a regional network of decentralised accreditation bodies. The core of such an alliance is the coordinated, voluntary cooperation between full-fledged accreditation bodies (ideally MRA/MLA signatories) and those that are being established. A formal arrangement that covers all legal aspects could be waived at least at the initial stage. Depending on the intensity of the cooperation and how the tasks are divided, the small accreditation bodies will function as notional accreditation focal points or accreditation partners without the independence of these bodies being questioned. The Central American Accreditation Forum (FOCA) is considered to be a model of this type of alliance. Initially the cooperation focused on technical collaboration, whereas the political foundation was developed at a later stage.

3. Creation of a regional accreditation body located on a central site and independently covering the accreditation activities of the whole region. This is a fairly recent endeavour with the first one in the world established in the Southern African Development Community (SADC) – see Box 8. The business model for SADCAS was designed in such a way that it neither competes with, nor contradicts, existing or future national accreditation body of individual member states. Rather it provides recognised accreditation services to those countries that don't have (and do not plan to establish) their own national accreditation body.

Therefore the opportunities for regional cooperation that arise from these options are manifold. They include the establishment of a regional database, joint training and joint accreditation with established accreditation bodies (i.e. twinning arrangements) thereby satisfying the demand for internationally recognised accreditation services in smaller countries inexpensively, whilst supporting the gradual establishment of competent national structures.

Box 9: The story of SADCAS

Most SADC member states are less economically developed, with small domestic markets that do not justify the establishment of a national accreditation body. Only South Africa has a fully functioning and internationally recognised accreditation body (SANAS), with Mauritius in the process of getting its NAB recognised. The regional accreditation body, SADCAS, was registered in Botswana in 2007 under guidance of the regional accreditation cooperation structure (SADCA). National Accreditation Focal Points (NAFPs) were established and trained in all the other SADC member states by using SADCA structures. The NAFPs act as competent contact points for potential customers in their own country. At the same time, a regional pool of experts was trained. The preconditions of international recognition are partly fulfilled by close cooperation with the international cooperation networks of ILAC and IAF through SADCA as the recognised Regional Cooperation Body. In order to speed up the international recognition process, SADCAS has entered into a 'twinning' arrangement with SANAS. This allows SADCAS to offer its clients an internationally recognised accreditation certificate, whilst at the same time gaining the practical experience it requires to satisfy the peer recognition process of ILAC and IAF.
Source: Contribution of quality infrastructure to regional economic integration, PTB

3.4.3 Regional Testing Laboratories

Standards and technical regulations in developed economies are becoming ever more sophisticated and the testing regimes to establish compliance are frequently state of the art. This presupposes sophisticated and expensive equipment, highly trained personnel, continuing high level maintenance and strict environmental testing conditions. In addition, even though these tests may be very important to regulatory authorities, they are not frequently required; hence the demand is quite low. In many regions it would therefore be difficult to establish a business case for creating such laboratories in each member state. Typical examples include dioxin and heavy metals testing of food products, or packaging test laboratories.

In such cases it may be useful to consider the establishment of a regional testing laboratory that could serve the whole of the region. Establishing a laboratory, although challenging from a technical perspective, should not be particularly problematic; however, the challenges that have to be overcome in making the laboratory operational are much more demanding:

- The logistics of getting samples from one country to another even within the regional context, i.e. rapid clearance by customs, obtaining SPS certificates on time and keeping the samples in pristine condition for testing are frequently intractable challenges;
- Obtaining foreign exchange in regions that do not yet have a monetary union can limit the amount of testing that the regional laboratory is able to conduct; and
- The decision in which country the laboratory will be established can lead to protracted and frustrating negotiations that eventually do not have an agreed outcome.

A related issue is the establishment of Proficiency Testing (PT) schemes. For laboratories to gain ISO/IEC 17025 accreditation, they have to demonstrate their proficiency in testing specific products by comparing results with a number of similar laboratories. In countries with many laboratories this is not an issue, but in smaller countries with only one or two laboratories of a kind, this is a stumbling block. Regional PT schemes are a useful way to deal with this challenge. The regional PT schemes could be managed by one of the more mature laboratories in the region or by one of the bigger national standards bodies or metrology institutions, fully supported by the regional accreditation services. Challenges similar to running a regional laboratory will be faced.

3.5 Regional Quality Policy

In addition to the three areas outlines above and depending on the way that regions operate in respect to policy instruments, it may be useful to consider the development of a regional quality policy or similar. Many regions take WTO TBT and SPS Agreement principles as a guideline to establish the trade rules, which usually include standards, technical regulation and conformity assessment requirements for the region. These rules come in many forms, e.g. the TBT Annex to the SADC Trade Protocol, the EAC Standardisation, Quality Assurance, Metrology and Testing Act, 2007 or the EU New Directives and Global Approach Directives. Whether a specific policy, green paper or white paper precedes the development and promulgation of such legislative instruments will depend very much on the custom and practice of the region.

The content of regional quality polices will of course be in part quite different to that of a national quality policy (see 2.1.1), especially the elements dealing with regional cooperation and coordination and any regional structures. The development of regional policies will also be much more demanding: It will have to follow processes specific to the region, the needs and aspirations of the member states of the region have to merge into a common approach, and a variety of political sensitivities have to be respected. Such issues therefore have to be considered carefully before the development of a regional quality policy is included in any project design.

4 Good Practices in Delivering Quality Infrastructure Related Technical Assistance

Sections 2 and 3 provide guidance on what a good QI should look like and how to establish it. This section looks specifically at how to prepare and implement technical assistance for developing countries to strengthen their QI, based on key lessons learned from development partners. The following good practices have been derived from published evaluation reports of QI projects and expert interviews. The results of the desk study were validated through an in-depth survey of the major development partners that currently provide support to QI development.

4.1 Project Preparation and Management

4.1.1 Building Quality Infrastructure and Long-term Planning

Embed technical assistance to building QI into a longer term plan, going beyond a single project phase. This also allows governments to mobilize their contributions to ensure that it is sequenced with international input. It is furthermore important to seek commitment and support for long-term strategies among key stakeholders, including the industry and NGOs.

Strengthening national QIs is a particularly long-term undertaking, which typically requires donor commitment beyond a single project. The international recognition process for accreditation bodies takes about 5 to 7 years (see also 2.4.1 above). Yet, short-term perspectives of development partners that are driven by donors' budget cycles of two to four years often negatively affect project results. Setting overambitious targets due to the need to quickly 'deliver' tangible results is a particular problem. Another undesirable outcome of short-term planning is a 'stop and go' of donor support, with gaps between different projects, during which parts of initial achievements may be lost. Patchiness of technical assistance without a clear overall plan may also lead to poor donor coordination, duplications among projects, and resource redundancy. The need for a longer term engagement is particularly evident where national QIs are at the very initial stage of development and the support required clearly exceeds the scope and length of one single intervention. Experience shows that achieving technical and financial sustainability of newly established quality institutions in particular requires sustained support over a longer period. Clear planning of donor support beyond the limited duration of one project gives partner countries the visibility needed to mobilise their own resources or to call on complementary donor assistance. Moreover, longer-term plans of donors that are widely shared with the government and the development community also contribute to enhancing aid harmonisation.

Good practice is thus to embed projects into a longer-term plan for assistance over several project phases. Planning should of course be aligned with beneficiary government's own planning, where available. The first project document should outline the longer-term objectives and briefly explain how the project intends to achieve them over time. For each project phase, clear, realistic intermediate objectives should be set. Funding of subsequent phases should be conditional to achieving intermediate objective. Ideally, input of periodic evaluations is used to adjust the overall strategy and to tailor subsequent project phases to evolving changes in context and needs.

Moreover, not only donor support may follow short cycles. Recipient priorities and strategies also shift with election cycles or changes in global policies. Donors should therefore seek widespread commitment and support for long-term strategies amongst key stakeholders, including the government, industry and NGOs.

4.1.2 Analyze Demand and Supply for Quality Services to Set the Right Priorities

Project preparation: Gain a clear understanding of demand and supply for quality services in the country or region to be covered by the project in order to set the right priorities.

Many, if not most, projects include components that aim at 'upgrading' quality institutions that provide quality related services (e.g. testing, certification) to serve the needs of the private sector. This is often expected to enable local companies to conform to quality standards and technical regulations - an important element of their competitiveness. In order to prevent redundancies and duplications, donor support needs to be geared towards strengthening those quality-related services that are in demand but not available or accessible for users. An example of duplication is the purchase of expensive testing or calibration equipment that is already available in the market and subsequently underused (see also 2.5.2 above). Another undesirable outcome of funding redundant capacities might be market distortion and crowding out of other, often private, service providers, where they exist. On the supply side, not all services necessarily need to be available domestically. For some highly specialised services, limited domestic demand might not justify significant investments into expensive equipment. In those cases, building service capacities is only justified where companies do not already have timely access to competitively priced services in neighbouring countries.

It is hence pivotal for project preparation to conduct an in-depth analysis of demand and supply of quality services in the country or region, not – as often done – simply assess the capacities of potential beneficiary institutions. For obvious reasons, this work is best undertaken by independent consultants rather than by potential beneficiary institutions. The analysis of demand refers to the specific needs of private and/or government clients (e.g. calibration of weight bridges). Supply means the services that are already available and accessible. Specifically, good project preparation should include (a) an analysis of demand by service and key users (b) a mapping of the available QI in the public and the private sector and (c) a gap analysis. On the demand side, it is of crucial importance to identify priority needs of both public and private sector clients, to ensure that their demands are met. The analysis of the supply side (mapping quality service providers) should include both the private and public sector. Once again, it should be emphasized that it would be mistaken to conduct a technical gap analysis of a specific potential partner institution (i.e. assessing what services it is not yet able to provide) without looking at other possible service providers.

Due to its complexity, context analysis often requires dedicated funding either for a preparatory or at least an inception phase. In practice, it is also advisable to look at information that has already been collected, either by other development partners, government agencies responsible for 'managing' service providers or NGOs (e.g. laboratory or metrology associations). As an additional caveat, beneficiary institutions that operate as profit centres are often interested in developing services that

are potentially most profitable. While such a focus may contribute to their financial sustainability, it may at the same time leave gaps in other areas that are critical for export capacity or consumer protection but which are not profitable enough for private players to provide. Stimulating but not distorting markets and taking into account the 'public goods' dimension of certain services are key guiding principles of any proper needs analysis.

4.1.3 Use National, Transnational and Regional Approaches Adequately

Use national, transnational and regional approaches as appropriate to the project environment. In strengthening regional quality systems, be aware that enhanced QI at the regional level does not disproportionally benefit the more advanced economies.

Transnational approaches aim at strengthening regional institutions, while regional approaches deliver assistance to several countries through a single project. Often, transnational, regional and national approaches are combined. This section looks at good practices on how to use regional or transnational approaches effectively.

Transnational approaches have been successfully used to strengthen regional cooperation frameworks or regional institutions (see section 3 above). Objectives of transnational projects have not been achieved where such a cooperation framework or regional institution was not in place. Moreover, experience shows that strengthening regional frameworks often requires support to the national QIs in parallel, to bring all countries to a level that allows them to participate and contribute to the regional framework. Delegating national functions to a regional body does not replace basic QI at the national level. Countries must for instance still be able to respond to certain basic metrology and testing needs. Specialisation of laboratories and other service providers in a region is meaningful, but only if those service are really accessible to users of all countries. Therefore, transnational support is often only effective if combined with support to individual countries. For details, please refer to section 3.2 and figure 8 above.

Regional approaches: By delivering assistance through one project targeting several countries, development agencies often aim at capitalizing on economies of scale and scope. Examples for economies of scale include sharing of expert resources (one expert for several countries) or sharing project overhead cost (e.g. one preparation mission, one shared project office for several countries). Economies of scope include the potential for exchanging experience and transferring know-how among countries ('South-to-South'). The expectation is that those target countries that still lag behind benefit from the expertise and experience of more advanced beneficiary countries. While this has worked well in certain cases, the flipside is that larger projects are more difficult to coordinate. Interests of countries are often not fully aligned, leading to 'competition' for resource allocation. Furthermore, regional projects are more difficult to design in a ways that cater to the needs of all countries. Logistics might be challenging as well (e.g. different languages require translations/interpretation). Designing regional projects that are of high relevance to all countries covered is particularly difficult in cases of 'asymmetric' economies which are in different development stages and/or lack common key industries. The need to design a 'one size fits all' project might lead to schematic designs that are unsatisfactory for everyone. The presence of a more

advanced lead country (e.g. Vietnam in the Mekong Region) through which know-how is transferred seems to facilitate regional cooperation, both formal and informal. On the other hand, political sensitivities (e.g. the risk that the lead country is perceived as too dominant) need to be taken carefully into consideration. Not only may a leading country be perceived as dominant, it may indeed be tempted to take advantage. Enhanced QI at regional level may have a disproportionately beneficial effect on the more advanced economy, and widen the gap among participating countries rather than narrowing it.

Economies of learning can be achieved by sharing experience among regional countries and economies of scale can be achieved by coordinating input (e.g. combining expert missions). A good way to benefit from the advantages of economies of scale and scope, while avoiding the pitfalls of a 'schematic approach', is to closely coordinate different individual (national) projects in one region. Good practice for both transnational and regional projects is to strengthen existing formal and informal regional cooperation structures between quality institutions in one region and to use expertise available in more advanced countries in projects in less advanced countries. The complexity of overlapping parallel management structures (delivering national projects via transnational structures) should be avoided. Transnational interventions (or project components) should consistently be implemented at the regional level, while national interventions should be implemented directly at the national level. Also, support needs to be carefully tailored to diverging needs of individual countries.

4.1.4 Work Through the Right Partner Institutions

Partner institutions for QI projects should be directly responsible for the technical fields they cover.

QI projects often cover a variety of technical fields that fall into the competencies of several organisations (see Sections 2 and 3). It is thus necessary to work with several partners. In order to ensure ownership, projects need to be 'anchored' within the right institutions. The selection of the right partner institutions is a crucial success factor. Experience shows that cooperation with organisations that are directly responsible for the fields addressed by projects is most effective. The selection of the counterpart organisation should not be influenced by factors such as historical bias, institutional rivalry or political considerations (e.g. 'our partner for trade-related technical assistance is always the Ministry of Trade' or 'we always work with the Ministry of Industry'). Institutional rivalries may include the case where an institution that is formally not mandated for a certain function tries to 'capture' most of the project benefits and does not include other key players. Both within and among institutions there can be exclusion and direction of resources to those 'whose turn it is next'. It is crucial to create win-win situations when building up new institutions or transferring responsibilities from one organisation to another (see 2.6 above). Identifying the right counterparts requires a careful mapping of the national QI.

4.1.5 Execution Modalities, Project Governance and Management

Define, agree and implement enabling governance and management structures for projects. Sound project planning, monitoring and evaluation are key success factors for development assistance projects in the field of QI, because they often address issues of high technical complexity through working with multiple partners. Active and diverse project steering committees add significant value. Beyond the project level, a formalised mechanism of donor coordination at country and regional levels is essential.

This section examines under which organisational arrangements QI projects are best delivered. It looks at good practices relating to implementation modalities, project governance and project management. Experience shows that success and failure of development cooperation projects in the field of QI development is often attributable to project governance and operational management, including the application of proper planning, monitoring and evaluation tools (e.g. logical frameworks)[32]. While this is true for all projects, the complexity of building QI makes this more general principle of good project management practice even more important. Clear terms of reference and separation of strategic management and day-to-day management were found to be important elements of good project governance. Good management practices with clearly defined decision making power that matches responsibilities and accountabilities are important as well. It should be noted that standardised implementation modalities might prevent some development agencies from applying some or all of the good practices identified below.

Implementation modalities: In line with their commitments under the Paris Declaration[33], many development agencies are gradually shifting towards some degree of national execution for their projects. National execution means that donor funds are channelled through the national system of beneficiary countries and that recipient governments have the final 'executive' responsibility for project implementation. Other new delivery modalities such as budget support and government led sector wide approaches are increasingly used as well (see summary of donor practices in Section 5). This brings new challenges for projects in highly complex technical fields, including building national QIs. Alignment may come at the price of reducing effectiveness and increasing rather than reducing transaction costs. For instance, national procurement systems are often not yet ready to cope with the sourcing of sophisticated technical equipment. Also, gaining access to highly qualified expertise is not an easy task for developing countries. The key challenge is to strike a balance between commitments to alignment of aid delivery and aid effectiveness, considering the specific absorption capacities of each country and institutions. Ensuring efficient and effective implementation of projects, while at the same time achieving a minimum degree of ownership and sustainability

[32] The correlation between successful implementation of quality infrastructure projects and proper application of project management tools is evidenced by almost all evaluation reports analyzed by the authors. As evidenced by the assessment of different multilateral partner institutions by NORAD shows, significant room for improvement remains: see Lindahl, C., NORAD, Norway's Trade Related Assistance through Multilateral Organisations: A Synthesis Study, Report 8/2011 – Study.

[33] Paris Declaration on Ownership, Harmonisation, Alignment, Results and Mutual Accountability, OECD 2005; http://www.oecd.org/dataoecd/11/41/34428351.pdf

through strengthening local structures, calls for delivery modalities that are tailored to institutional capacities of counterparts. Where development agencies can choose between delivery modalities, forms of 'joint-execution' or 'mixed execution', combined with mutual accountability seem to work best. Sub-contracting elements of projects to local counterparts seems to be a good way to gradually move towards more partner-led implementation, as are forms of joint-decision making. Due to often cumbersome procurement procedures in developing countries and the difficulty of accessing international expertise, sourcing highly qualified expertise and equipment is however best done by the international counterpart.

Project governance: Since building QI involves many different stakeholders, active and diverse project steering committees add significant value. Within the steering committee, functions of 'stakeholder involvement' and decision making at strategic level should not be mixed. Changes to project agreements can only be made by its signatories. The tension between involving many stakeholders in project steering and blurring decision making power might be resolved by dividing the Steering Committee into voting and non-voting members. Including representatives from other donor-funded project as observers is a good way to improve informal donor coordination. Steering committees should be kept informed of all important financial data in order to make well-informed decisions. Sharing financial data with counterparts is also a good way of capacity building, as it allows counterpart institutions to gain experience in planning their own projects in the future.

Operational management: At the operational level, a delegation of day-to-day management to the 'field level' worked generally best. If day-to-day management of projects is delegated to the field, headquarters of development agencies can reallocate resources from operational management to backstopping, transferring know-how and capacity building, and providing selected services that cannot be sourced locally (e.g. equipment procurement, retaining international experts). Rather than focusing on micro-management issues, managers could concentrate on more value-added inputs of primary importance (strategic orientation of projects, identifying opportunities for new projects, political/policy questions).

This requires the selection of a local coordinator or adviser with strong leadership skills, knowledge of the local context and ideally also of the local language, rather than only technical specialists. In contrast, centralised project management approaches from the headquarters of development agencies often lead to delays and a lack of counterparts' ownership and motivation. On the other hand, remuneration packages are often not competitive and longer-term career perspectives are limited. Hence, many development agencies find it challenging to attract top candidates as local coordinators.

Embedding project offices into key counterpart institutions and empowering them to make day-to-day management decisions seem to work best. In case a project works with multiple partners, this model might not always be practical, although it has been successfully applied in some countries.

Where decision making power is delegated to the field or counterparts, implementation risks need to be minimised through strengthening financial (assurance/audit) and operational monitoring systems. The European Union for instance complements evaluations with Result-Oriented Monitoring

(ROM)[34]. The task of monitoring complex projects may be commissioned externally, at least for strategically important projects with high implementation risks. Project governance and management structures should be agreed by all project partners prior to implementation.

4.2 Strategic Approaches to Support Quality Infrastructure Development

4.2.1 Strengthen Demand and Supply of Quality Services in Parallel

The most effective way to develop quality systems is a two-pronged approach that combines strengthening demand and supply for quality-related services in parallel.

Anecdotal evidence suggests that quality demand is clearly an important driver for the development of national QIs, yet often insufficiently addressed as it is frequently given low priority by donors.

Important domestic 'quality drivers' are for instance consumers, local export firms, international investors and international buyers who call for improvements in the national QI and monitor their implementation. Quality-conscious societies have mechanisms for (a) consumer protection and (b) involvement of consumers in formulating quality policies. The consumer – not only government management agencies - has an important role in identifying sub-standard products (e.g. under weight, wrongly labelled). Consumer pressure tends to drive better quality and compliance with standards. The concept of consumer rights is relatively new, but evolving, in developing countries. One reason for this is that policy makers recognise that the poor, who have less ability to make economic choices, are disproportionately punished by sub-standard products. Weak capacities of consumer organisations to represent their interests are often identified in the project development phase, but typically only limited resources are then allocated to addressing them.

Some development partners have specifically focused on strengthening consumers' rights[35], although their associated projects are not formally linked to interventions strengthening quality infrastructure.

Box 10: Examples of projects aimed at building a 'quality culture'

- In Tanzania, UNIDO developed a curriculum and training material to integrate food safety/quality aspects into existing food science and technology courses for high school students. The idea was to achieve a spill-over into more general quality awareness among future professionals. While the material was successfully used in one particular school, integration into official national curricula and a roll-out to other schools failed, because the activity was not sufficiently coordinated with the Ministry of Education.
- With support from UNIDO, Cambodia established an internationally accredited 'product certification Scheme' for bottled water, hosted by the Cambodian Standards Board. Combining

[34] See European Commission, EuropeAid Co-operation Office, ROM Handbook Results-oriented Monitoring, April 2012. Switzerland is in the process of piloting ROM in some projects.

[35] Examples include Switzerland, the Netherlands, Japan and the United States. A number of projects implemented by UNIDO include the strengthening of consumer organisations, yet support was rather limited.

project certification with promoting the mark among companies and consumers was identified as one of the key success factors of product certification schemes.

- UNIDO supported the National University of Togo to introduce a quality curriculum for post graduate science and engineering students as well as short courses for industry practitioners. Increasing the availability of expertise for companies aimed at strengthening demand for quality among the private sector and ultimately led to higher competitiveness of the economy.
- In Cote d'Ivoire, UNIDO supported a broadcast and awareness raising programme, explaining basic functions of the national QI (e.g. the calibration of weights).
- In different countries, UNIDO provided support to national quality award programmes.

Source: UNIDO, Thematic Evaluation of UNIDO activities in the area of SMTQ, Vienna 2010

A two-pronged approach that strengthens both the demand for quality services and the ability of the national QI to respond to it in parallel seems to be most effective. Strengthening demand for quality services requires, besides the consumer aspect, building a 'quality culture' among companies and the broader population. Successful examples of include:

- Support to national quality forums and quality awards
- Strengthening consumer protection organisations and competition authorities
- The establishment, accreditation and promotion of quality marks
- Public education and awareness raising on quality issues (e.g. on TV or radio)
- Work with training institutions to mainstream quality issues into curricula (at all levels)

4.2.2 Addressing Competitiveness Constraints Comprehensively, beyond Quality Infrastructure

Achieving a positive impact of quality infrastructure on trade and private sector development requires addressing all key factors enabling businesses to successfully compete, where necessary through cooperation among different development agencies. Selective development of quality infrastructure elements relevant to *specific value chains* is an innovative approach that worked well where a basic quality infrastructure is already in place.

What makes businesses competitive? Many QI projects aim at trade capacity building, i.e. enabling companies to successfully market their products domestically and internationally. Successful businesses are able to meet the quality standards required by the market ('conformity') and sell at prices that provide an adequate return on the capital employed in producing them ('competitiveness'). Finding buyers through successful marketing of products refers to the 'connect' aspects of trade capacity building, which are equally important. Accessibility of quality-related services to companies (e.g. testing, industrial metrology, certification etc.) is pivotal for the 'conformity' aspects (meeting standards required by the market). In addition, they are also relevant for ensuring productivity and product quality, which are both elements of 'competitiveness'. This explains the importance of addressing 'compete, conform and connect' capabilities of local businesses comprehensively and in parallel, if necessary through cooperation among different development partners. Another important competitiveness factor is access to finance for investments into state-of-the-art equipment that is needed to produce high quality goods efficiently.

Assisting companies to 'conform', the primary expected outcome of a well-developed QI, alone is not sufficient. An element still largely ignored in most projects is the lack of cooperation between Quality Institutions and Trade Promotion Organisations, which would offer tremendous synergies.

Box 11: Lebanon - The importance of packaging in rapidly industrializing economies

An excellent way to make a real change for all types of businesses is the provision of 'packaging services'. Recognising this importance, UNIDO provided support to LibanPack https://libanpack.org, a non-profit private sector association representing stakeholders from the food and packaging sectors in Lebanon. Inappropriate packaging and labelling was identified as the key reason for rejections of Lebanese export goods to the European and U.S. markets. Advice on how to label and package products results in an immediate creation of value for various scales of companies, perhaps with the exception of the informal sector. Beyond this, packaging helps companies to add significant value to their products and to increase sales prices in the domestic market.
Source: UNIDO, Thematic Evaluation of UNIDO activities in the area of SMTQ, Vienna 2010

A 'holistic' project approach to assist businesses is even more important, as all three aspects of 'trade capacities' are closely interlinked. For example, obtaining management system certifications (such as ISO 9000 or ISO 14000) not only helps companies to conform to standards required by importers, but also tends to contribute to increased productivity. Attractive packaging, as another example, adds value to products and increases their marketability, while conformity with packaging requirements is crucial for product quality and international market access. Evaluation findings confirm that comprehensive 'trade capacity building projects' work significantly better than 'delivering' different aspects through separate interventions. Where such a 'holistic approach' is not possible and projects rely on a combination of support provided by different development agencies, 'linkages' between projects need to be formalised by defining specific joint-activities.

Value chain approaches: Examples of good practice also include projects that are based on a value chain approach, especially in countries where a basic QI is already in place. Often however, there is still a need for enhancing the competitiveness of certain specific industrial sectors, including the ability of the industry to comply with standards. In such cases, a less traditional approach is to identify quality-related weaknesses along specific value chains. The 'value chain concept' looks at the activities of an organisation or an industry used get products to market. Value chain activities are operations that transport or transform elements of the final product. The primary value chain activities are sourcing, inbound logistics, operations (transforming inputs into finished products and services) and outbound logistics. Businesses and industries are successful when the total value added throughout the value chain is higher than (a) the cost of those activities and (b) the value added by competitors. These primary activities are either supported or constrained by policies and the legal and regulatory framework, including the QI. Thus, a favourable macro-economic climate and regulatory framework is crucial to strengthen competitive advantage of the local industry. For many products sold in international markets, the profits are greater at the later stages of the chain, with the country that is the source of the raw materials gaining the lowest percentage of value. In order

to boost economic development of exporting countries, value chains need to be reconfigured in a way that more value is realized at the early stages of the chain.[36]

The value chain approach has the advantage that the needs of users of quality services, as opposed to the perceived needs of quality service suppliers, are at the core of the project. This lowers the risks of duplications, redundancies and of building QI that might not be of use to key industry sectors. Furthermore, working along value chains also increases chances that all key challenges along the value chain (not only those relating to weaknesses in QI in a narrow sense) are identified and potentially addressed (if needed in cooperation with other development agencies). The value chain approach seems to be particularly adequate for countries where a basic QI is already in place and the objective is to selectively enhance certain elements of it to better meet the needs of key industry sectors.

Box 12: IFC - Performance improvement through standards compliance along value chains

The IFC's Environmental, Social, and Trade Standards teams assists firms to improve performance and reduce cost through implementation of good practices and efficient verification and certification schemes in their supply chain. The IFC works with public and private stakeholders to increase the adoption of standards by:

- Demonstrating to firms the benefits of standards through the implementation of good practices
- Training firms and their supply chains on adopting standards
- Promoting the adoption of standards among firms, governments, and NGOs
- Undertaking benchmarking of standards to promote harmonisation, reduce cost of duplication and increase knowledge
- Collaborating with financial institutions, industry groups, and other market aggregators to scale up investment in standards adoption
- Promoting and developing standards for different industry sectors, such as the 'Roundtables for Agro-Commodities'
- Analyzing and supporting policy and regulatory needs on standards, such as Food Safety and national interpretation of international standards.

Source: Factsheet, IFC Advisory Services in Sustainable Business, Environmental, Social and Trade Standards, Washington, January 2013

4.2.3 How to Provide Support to Businesses?

Strengthening business service providers (intermediaries) is more effective and sustainable than direct support by projects. Careful consideration should be given to the question whether to strengthen private or public sector business service providers.

[36] Adopted from methodology described in Project Document, 'Increasing Trade Capacities of selected value chains within the Fisheries Sector in Indonesia', funded by SECO and implemented by UNIDO.

Companies often need external support (business development services) to benefit from QI, e.g. to conform to standards required by their clients and by compulsory regulations of both domestic and export markets. In many countries, such services are however not readily available or not affordable, in particular not to SMEs. How should projects tackle this need?

The insight that direct and free consultancy services provided by donor-funded projects are problematic in various ways is not new. Firstly, direct service provision through projects may lead to market distortion and crowding out the fledgling local consulting sector. Secondly, without developing local consultancy providers in parallel, it is hardly sustainable – there is a high risk that service delivery ends at the time that funding stops.

While pilot consultancy projects at the enterprise level (e.g. in obtaining quality system certification, e.g. ISO 9000) might be justified to build business support capacities of public partner institutions, the question is whether 'consultancy support' is really a public function that should be strengthened with development aid, potentially to the detriment of fledgling private service providers. Most development partners seem to agree that strengthening local private and public institutions (intermediaries at the meso level) that are expected to continue providing services to companies beyond the end of donor support is a good practice. However, the situation in LDCs with not enough demand for consultancy services and no private consultants might justify strengthening public institutions as business development service providers, in order to create initial demand for business support services.

4.2.4 Expand Project Benefits to SMEs and Rural Areas

Ensure that benefits of support expand beyond large companies in key sectors.

Internationally competitive large-scale businesses are easy to identify and reach, and chances to achieve an immediate success story are higher. Thus, the temptation is to focus on the low hanging fruits. Working with small scale enterprises - whether exporters or suppliers of exporters or traders in the local market - is more challenging. Small-scale businesses are however an important part of the economy and should not be left out. Reaching smaller businesses is a sign of success because it indicates the ability to reach nascent and emerging industries. The importance of start-up businesses and small industry for job creation and innovation is well known. A well-developed national QI should reach beyond lead industries and sectors.

In the field of metrology, mobile calibration and metrology services (currently used in Ethiopia, Mozambique and Bangladesh) may be a way to improve the reaching out of calibration laboratories to SMEs in rural areas. The challenge is to balance the objective of developing NQI that meets the needs of all business scales with approaches needed to 'get things started', which may include beginning with focus sectors and larger-scale companies.

4.3 Support to Quality Institutions

The following section provides some good practices in strengthening quality institutions.

4.3.1 Combine Technical with Institutional Strengthening of Quality Service Providers

Ensure a combination of both technical and institutional strengthening of quality service providers. This includes in particular good governance, business planning and human resource development strategies.

Sections 2 and 3 describe the different elements of an enabling QI. In practice, support by development agencies often overemphasises the technical capacities (e.g. provision of testing equipment, training of laboratory specialists, obtaining accreditations, etc.), while omitting institutional aspects. In addition to 'technical' aspects, institutional strengthening and advocating for an enabling legal framework should therefore be included into the mix of intervention tools for upgrading public service providers. For instance, the way that national quality system institutions are governed and managed affects the quality and credibility of services. Many projects identify substantial institutional weaknesses during the design and inception phase as a project risk, but then do not address the root causes. Institutional strengthening through projects should include both policy advice and hands-on management support, including business plan development and implementation. Staff turn-over, often due to low salaries or the lack of long-term professional development opportunities, jeopardizes technical sustainability of project results (see also 2.1.6 above). It is therefore also crucial to assist quality institutions in developing human resource development plans that are conducive to retaining staff (e.g. through appropriate remuneration packages). Assisting institutions, many of which are originally former administrative authorities, to adopt governance and management structure that makes them credible and client-oriented is of particular importance. An 'organisational assessment' of beneficiary institutions is a good way to start and to identify specific priority needs.

'Institutional capacity building' in a broader sense may include:

- Advocacy and advice on suitable governance, typically involving prominent industrialists at the strategic management level. It is also crucial to avoid conflict of interests.

- Advice on management models. For public service providers, a certain degree of autonomy is important because it allows for the flexibility to respond to the demands of the market, reduces the risk of political interference and therefore makes institutions more credible in the eyes of potential clients and partners, and ensures that they respond to the real needs of the sectors that they are mean to service. There are different models for financial autonomy, including institutions that remain within the core administration but are allowed to keep a percentage of revenues through to public service providers operating under a public company model. In between, there are various mixed forms. Financial and organisational autonomy contributes to the effective operations in several ways. Firstly, there is an incentive to improve the quality of service and better cater to customer needs. Secondly, service providers are independent from complex and time consuming budgeting and procurement regulations which often plague public

bodies in developing countries (e.g. for purchasing of material, equipment, repairs, etc.) and flexible in adapting to changing demands. Thirdly, the autonomous status frequently also allows for some flexibility with regard to hiring, dismissing and remunerating staff, which is a condition for building and retaining a pool of qualified experts (outside staffing plans of the government). Projects might assist governments and institutions to develop a suitable model, which of course needs to be in line with the legislation on public management and ongoing public administration reforms.

- Hands-on management support. Where former administrative authorities are to be transformed into client-oriented service providers, training and hands-on support in building management capacities is important. Examples include business planning, marketing of services, financial management, managerial accounting etc.). Otherwise, there is a risk that those institutions will, despite an enabling legal status and state-of-the-art facilities, fail to sustain themselves as independent service providers, which in turn would jeopardize their sustainability

- Business plans. Well managed institutions have 'business plans', prepared according to best practices in enterprise management, which are then actively applied. These plans provide visions, aims, businesses goals and focus, demonstrate understanding and responsiveness to market demand and outline the difference between core and peripheral activities. Organisational structure should follow the business strategy (not political considerations). Well-drafted business plans include a detailed market assessment (demand and supply), as well as financial projections (pro-forma income statements, balance sheets, and cash flow statements). The business plan should clearly state the source of funding for both operational expenses and investments and provide evidence of sustainability of those. Only institutions that are able to cover basic investments into machinery and recurrent expenditure are sustainable.

4.3.2 Promote the Credibility of Quality Institutions

Projects should facilitate the engagement of beneficiary institutions with more advanced peers in third countries.

Successful national quality institutions are recognised internationally, reflected in their certificates and accreditations (see section 3.1). The two key building blocks of credibility are mutual recognition agreements (MRA) and accreditation. Tests and certificates need to be recognised in the country where the product is sold. There are three ways to do this: 1) certain bodies either recognize each other's CA results as equivalent to theirs through a bilateral recognition agreement based on peer-assessment or 2) they are part of a multilateral recognition agreement (MLA) and recognize the certificates issued by all the other members to that MLA which is also based on peer-assessment or 3) the two bodies can be accredited and decide to recognize each other's certificates.

A donor focus on supporting institutions in getting accredited is therefore important. A good way of promoting international credibility and anchoring institutions in international networks is 'twinning' them to more advanced peers in other countries. Twinning with other more advanced regional institutions, e.g. within a regional project approach is particularly promising. However, successful

twinning of institutions requires a certain level of institutional maturity of the partners. The EU for example, applies the twinning concept mainly in more advanced countries rather than in LDCs. Governmental stability and long-term commitment of institutions are also important factors.

See also sections 2.2, 2.4 and 2.5 above on twinning arrangements as a good practice in metrology, accreditation and conformity assessment.

4.3.3 Maintenance and Operating Cost of Expensive Laboratory Equipment

Address the problems of maintenance and operating costs of expensive laboratory equipment at the project design stage.

Equipment provision and financial support to accreditation for laboratories are often a core element of QI projects. Yet sophisticated technical equipment needs regular maintenance, often of a specialist nature unavailable in the recipient country and therefore expensive. Funding for this is often not available. The purchase of consumables for testing equipment can be challenging for institutions with either small recurrent budgets or no flexibility to use income earned for recurrent expenditure. Another particular problem is the recurrent costs of certification and accreditation from third parties. For quality institutions, these costs can be substantial (e.g. many different laboratories and many different areas that have to be inspected and renewed every year). The lack of funds to ensure all of this is often identified as a risk for sustainability, but afterwards not addressed. Even where funding for repair is available, it is sometimes difficult to get timely access to repair services e.g. where equipment suppliers are based on the other side of the world and have no local representation. To the degree possible, the donor community should cooperate to focus on a limited number of different equipment manufacturers. It is far less costly to get a technician from abroad to service several pieces of equipment, than getting several technicians to each service their own (see also 2.5.2 above).

Good practices include:

- Communicate procurement plans to beneficiary institutions in order to enable them to coordinate different donor assistance and apply for funding from the state budget, where available.
- Where beneficiaries are responsible for upgrading laboratory buildings (e.g. installation of air conditioning, uninterrupted power supply), specification should be defined in detail and agreed upon prior to commissioning equipment.

Box 13: Donor preference to equip laboratories – yet insufficient awareness on sustainability issues

'(…) Donors have insufficient awareness of the activities and costs associated with sustaining laboratory capacity to a required standard (that is accredited to ISO/IEC 17025). Almost 100% of the operational cost of a testing laboratory are fixed costs, and therefore need budgetary support of the beneficiary, which is rarely in place. As a result there are numerous examples of laboratory equipment supplied to testing laboratories but not used due to lack of training, service support,

spare parts, and operating budgets for calibration, proficiency testing, accreditation fees and reagents. Yet the assumption persists that laboratory equipment continues to be an important part of TCB requests and projects in this area. In the worst case scenarios donor ignorance and lack of attention to these details have perpetuated conflicts of interest in laboratory management. (…)'
Source: Golding I, 'Compliance related challenges in international trade on fishery products'. Paper prepared for the conference, Re-Visiting UNIDO TCB Approach, UNIDO, November 2009, cited by UNIDO, Thematic Evaluation of UNIDO activities in the area of SMTQ, Vienna 2010

- Assist institutions in establishing a costing/pricing system that takes maintenance, operating and amortization cost of equipment as well as the cost of renewing accreditation into account.
- Where institutions have not yet access to sufficient financial means, it might be an option to fund extended maintenance warranty packages together with equipment.
- Selection of equipment for which the supplier provides on-site warranty and maintenance (to be included into the technical specifications for procurement), preferably through agents within the country or region.
- Support to the establishment of facilities that can provide basic maintenance services, either within institutions or for several laboratories. For centralised repair facilities, a clear 'business plan', governance structure that represents key clients and contractual arrangements are crucial (otherwise, an investment is made and some institutions might resist using the service).

For LDCs with very limited access to state funding – or sometimes even to hard currency - and where clients are not able to pay for cost-covering prices, incorporating gradually decreasing financial support for operating equipment into project support might be the solution. A clear plan for a gradual phasing out is however essential.

4.3.4 Institutionalized Training Functions

Move from direct staff training or 'training trainers' towards institutionalising training functions in key institutions or to support formal training of specialists. Twinning international with national experts is an effective and sustainable way to achieve know-how transfer.

Support to establishing a well-functioning QI often involves extensive staff training. Maintaining practical skill levels in fields that are subject to frequent technological changes requires establishing structures that allow for ongoing training in partner institutions beyond the limited scope and duration of a project.

Most projects use a so called 'train the trainer' approach as a way to multiply impact of trainings. The follow-ups on such trainings however, i.e. how the specialists trained would transfer their know-how, is often not taken into consideration. Many participants in 'study visits' and courses, especially high level officials, are unlikely to have the time to give trainings.

A good practice found in evaluation reports was to shift from a traditional 'train the trainer' approach to the strengthening of dedicated training divisions within key institutions. Another way to improve the effectiveness of the 'train-the-trainer' approach is to include follow-up trainings given by trainers as a project activity (use of laboratory experts trained as project experts for other laboratories). Twinning international with national experts is an effective and sustainable way to achieve know-how transfer. Institutionalizing training within counterpart institutions might be an effective way to extend the impact of trainings beyond a limited number of persons and time. It also mitigates to some degree the commonly encountered problem of staff turnover (staff leave or move to other positions after receiving training). Another good way to ensure sustainability of trainings is to support technical universities in offering specific curricula for quality specialists (e.g. metrology, testing, and standard setting).

4.3.5 Strengthen the Pool of Expertise though Supporting Communities of Best Practices and Knowledge Portals

Development agencies should support the development and exchange of expertise through 'communities of best practices'. Knowledge portals are a good way to collect and promote good practices in strengthening QI.

As in other highly specialised fields of donor support, experts with a combination of a technical and development background are scarce. Most development agencies find it increasingly difficult to recruit the right specialists, in particular for longer-term positions. Furthermore, the ongoing changes in how QI systems work internationally require a constant upgrading of professional knowledge.

Good practices include regular international conferences to exchange best practices among experts in the field of quality infrastructure development. Examples for activities to strengthen 'communities of good practice' are the regular meetings for Technical Advisers organised by UNIDO and PTB. Allowing younger professionals to work alongside their more experienced peers is a good way to strengthen the expert pool development agencies are able to call upon for the implementation of their projects.

5 Priorities and Specialisation of Donors and Implementing Agencies

Donors and development agencies have specialised in specific QI elements. Considering their particular core competencies allows beneficiary countries to source the right type of assistance for their specific needs. Coordination of efforts and a division of work among donors and development agencies also contribute to the internationally agreed principles of aid harmonisation and effectiveness. Derived from a survey among a number of key development actors in the area of QI-support, this section provides an overview on technical areas covered, services provided, expected results and delivery modalities.

5.1 Technical Areas Covered

Area always covered ● Area often covered ● Area sometimes covered ● Area not covered X	EU	FAO	Germany (PTB/GIZ)	Netherlands	Norway	SECO	UNIDO	World Bank
Legal and institutional arrangements in general (laws, institutions)	●	●	●	●	●	●	●	●
Quality policy development	●	●	●	●	●	●	●	●
Accreditation bodies	●	●	●	●	●	●	●	●
Standards	●	●	●	●	●	●	●	●
Technical regulations	●	●	●	●	●	●	●	●
Metrology Institute (as separate entity or part of another)	●	X	●	X	●	●	●	●
Legal metrology	●	X	●	X	●	●	●	●
Industrial metrology (e.g. calibration services)	●	X	●	X	●	●	●	●
Conformity assessment: inspection	●	X	●	●	●	●	●	●
Conformity assessment: testing	●	X	●	●	●	●	●	●
Conformity assessment: certification	●	●	●	●	●	●	●	●
Food safety	●	●	●	●	●	●	●	●
Private standards	●	●	●	●	●	●	●	●
Quality Promotion / Awards					●	●	●	●
Consumer Protection					●	●	●	●

5.2 Types of Support Provided

Always provided ● Often provided ● Sometimes provided ● Never provided X	EU	FAO	GIZ	Netherlands	Norway	SECO	UNIDO	World Bank
Financing quality infrastructure reforms (e.g. loans and grants to beneficiary countries without technical support)	X	●	X	●	X	X	X	●
Research and analysis	●	●	●	●	●	●	●	●
Advocacy	X	●	●	●	●	●	●	●
Legal advice	●	●	●	●	●	●	●	●
Technical advice to quality institutions	●	●	●	●	●	●	●	●
Other institutional strengthening (e.g. management advice & training)	●	●	●	●	●	●	●	●
Study/exposure visits for staff of quality institutions	●	●	●	●	●	●	●	●
Staff training on site for quality institutions	●	●	●	●	●	●	●	●
Staff training off-site (e.g. attachment trainings) for quality institutions	●	X	●	X	●	●	●	●
Advise in sourcing equipment (e.g. drafting technical specifications)	●	●	●	●	●	●	●	●
Equipment provision (e.g. upgrading laboratories)	●	●	●	●	●	●	●	●
Advise and training relating to accreditation	●	●	●	●	●	●	●	●
Covering accreditation cost of quality institutions	●	●	●	X	●	●	●	●
Covering certification cost of quality institutions (e.g. ISO 9000, 14000, etc.)	●	X	●	X	●	●	●	●
Covering certification cost of enterprises (e.g. ISO 9000, 14000)	●	X	●	X	●	X	●	●
QI support integrated into broader private sector development projects	●	●	●	●	●	X	●	●
QI support integrated into broader business environment reform projects	●	●	●	●	X	X	●	●
QI support integrated into projects aiming at strengthening specific value chains	●	●	●	●	●	●	●	●

5.3 Direct Target Beneficiaries

Always targeted ● Often targeted ● Sometimes targeted ● Never targeted X	EU	FAO	GIZ	Netherlands	Norway	SECO	UNIDO	World Bank
Government level (ministries and above)	●	●	●	●	●	●	●	●
Accreditation bodies	●	●	●		●	●	●	●
Standard bodies (responsible for standard formulation)	●	●	●		●	●	●	●
Inspection bodies (enforcement of mandatory standards)	●	●	●		●	●	●	
Metrology Institutes (national measurement standards)	●	X	●		●	●	●	●
Metrology institutions (legal metrology)	●	X	●		●	●	●	●
Metrology laboratories (industrial metrology – e.g. calibration)	●	X	●		●	●	●	●
Providers of system certification services (e.g. ISO 9000, ISO 14000)	●	X	●		●	X	●	●
Providers of product certification services	●	●	●		●	X	●	●
Testing laboratories	●	X	●		●	●	●	●
Enterprises (direct services provided)	●	●	●	●	●	X	●	●
Intermediaries (organisations providing services to companies)	●	●	●	●	●	●	●	●
Enterprise associations/chambers	●	●	●	●	●	●	●	●
Consumer organisations	●	●	●		●	●	●	●
The broader public (e.g. awareness raising activities)	●	●	●	●	●	●	●	●
University and other training institutions	●	●	●	●	●	●	●	●
Banks and local finance institutions	X	●	X	●	X	X	X	X
Regional Economic Communities (REC)	●		●		●	X	●	●

5.4 Expected Main Outcomes

Always indicated as expected outcome ● Often indicated as expected outcome ● Sometimes indicated as expected outcome ● Never indicated as expected outcome X	EU	FAO	GIZ	Netherlands	Norway	SECO	UNIDO	World Bank
Legal framework (including policies) relating to quality and technical regulation enhanced	●	●	●	●	●	●	●	●
Quality infrastructure institutions better able to fulfill their functions	●	●	●	●	●	●	●	●
Training institutions teach quality-related competences to specialists	●	●	●	●	●	●	●	●
Awareness on quality among broader population raised	●	●	●	●	●	●	●	●
Awareness on quality among enterprises raised	●	●	●	●	●	●	●	●
National quality fora strengthened (e.g. organisation of high-level panels/events attended by public and private decision makers with the aim to promote awareness on quality)	●	●	●	X	●	●	●	●
A system for quality rewards (e.g. for companies) established / strengthened	●	●	●	X	●	●	●	X
Consumer organisations strengthened	●	●	●	X	●	●	●	X
Capacities of companies to comply with standards improved	●	X	●	●	●	●	●	●
Capacities of intermediaries (service providers to companies) strengthened	●	●	●	●	●	●	●	●
Product quality aspects within a specific value chain strengthened	●	●	●	●	●	●	●	●
QI services or institutions gaining international recognition			●		●	●	●	●
Number of requests for QI services increased			●		●	X	●	●
Service quality aspects within a specific value chain strengthened			●		X	●	●	●
Cooperation between national /regional QI institutions increased			●		●	X	●	●
Increased access to quality infrastructure				●	●	●	●	●

5.5 Expected Main Impact

Always indicated as expected impact ● Often indicated as expected impact ● Sometimes indicated as expected impact ● Never indicated as expected impact X	EU	FAO	GIZ	Netherlands	Norway	SECO	UNIDO	World Bank
Increased private sector compliance with related legal and regulatory framework	●	●	●	●	●	●	●	●
Increased investments in innovative products and services	●	●	●	●	X	X	●	●
Increased trade flows due to the harmonisation of national legal and regulatory framework with international standards	●	●	●	●	●	●	●	●
Increased number of jobs in innovative enterprises	●	●	●	●	X	●	●	●
Improved environmental protection, energy efficiency, consumer and health protection			●		●	●	●	●
Increased private sector competitiveness			●		●	●	●	●
Poverty reduction/wealth creation				●	●	●	●	●
Improved business climate/private sector development				●	●	X	●	●
Reduced border rejections					●	●	●	●

5.6 Fund Management and Cooperation Arrangements

Always used ● Often used ● Sometimes used ● Never used X	EU	FAO	GIZ	Netherlands	Norway	SECO	UNIDO	World Bank
Funds managed and overall project responsibility by beneficiary country/organisation:								
General budget support to beneficiary governments/organisations	X	X	X		X	X	X	●
Grants managed by counterpart institutions ('National Execution')	●	●	X	●	X	X	●	●
Conditional loans provided to beneficiary governments or institutions	X	●	X	●	**X**	**X**	X	X
Funds managed and overall project responsibility by the donor/international development agency:								
Funds directly managed by the donor	X		●	●	**X**	**X**	X	●
Funds managed by a national public institution on behalf of the donor/international development agency	●	●	X	●	**X**	**X**	X	●
Funds managed by a multilateral institution on behalf of the donor/international development agency	●	●	X	●	●	●	●	●
Funds managed by private sector company on behalf of the donor/international development agency	●	●	X	●	X	X	X	X
Joint fund management and overall project responsibility								
Shared responsibility between donors/international organisations and beneficiary countries (e.g. joint-decision making, but funds managed by an institution/organisation appointed by the donor/international development agency)	●	●	●		●	●	●	●
Public-private partnerships								
Co-funding of projects with private sector	X	●	●	●	X	X	●	X
Partnerships between development agencies								
Strategic 'sourcing' of services from other agencies to complement the own technical approach	X	●	●	●	X	X	●	●

6 Outlook

The way in which the quality infrastructure and technical regulation is organised has changed quite dramatically over the past few decades. An 'integrated approach', i.e. standards, metrology, inspection, testing and certification and even technical regulation (i.e. mandatory or compulsory standards) provided by a powerful national standards body, was very much the norm twenty years ago. This however, is no longer an acceptable approach, even in developing economies with their stretched resources. In a world of open trade and value chains that routinely cross national boundaries, countries have to be more outward looking; moreover, conflicts of interest inherent in such an integrated approach have become problematic. New ways to organise the quality infrastructure and technical regulation regimes at the national level have had to be found. The practices described in this publication are based on these new realities.

ISO and IEC made a significant contribution in the decades after World War II to harmonising international standardisation efforts. But developing international standards takes time due to the consensus that has to be achieved, and competing industries are not always happy with the outcome. In parallel, private standards developed by multi-nationals emerged. They are quicker to market, and in many cases serve the business interests of their developers better than international standards do. Private standards were initially shunned by national and international quality infrastructure organisations, but this is no longer realistic. On the other hand, market realities and increasingly internationalised value chains force players to agree standards amongst each other and require international harmonisation. The pace of these developments will quicken in the years to come as value chains become even more internationalised. Private standards however are very numerous, sometimes contradicting each other and are often not well known by those that are not yet part of international value chains. Development partners, in cooperation with private sector fora, have started to facilitate the harmonisation of private standards in areas such as food safety, but there is still much work to do. Initial good practices are emerging and being successfully applied.

Another development that has a profound impact on quality infrastructures and technical regulation is the growth of trading blocs. Within a trading bloc, goods and services need to move freely from one country to the next. This is only possible if the standards and technical regulations of the member states are the same. What is inspected, tested and certified in one member state should be accepted without reservation in all other member states. This is putting pressure on the public metrology and accreditation infrastructure and conformity assessment services, especially in smaller economies. Regional standards based on international standards are fairly easy to adopt. Providing the physical infrastructure for a decent metrology service however, is much more challenging. The same applies to the more sophisticated testing services and accreditation. Hence, regional structures that can provide a service to the whole trading bloc, or at least to its smaller economies, are beginning to emerge. That in turn however requires creating a clear division of labour between countries and institutions, which is often challenging. Harmonisation of conformity assessment methods and procedures will be needed to facilitate mutual recognition of conformity assessment

results. This development is still in its initial stages and prejudices still have to be overcome, i.e. political sensitivities getting in the way of good business sense. Clearly though, the realities of a common market and the cost of establishing and maintaining technologically sophisticated services are driving change. As trading blocs integrate more and more in the years to come, regional service delivery will become more prevalent. Development projects will have to be mindful of these changes in the trade environment; they will have to further conceptualize an innovative approach to regional cooperation and division of labour in the area of quality infrastructure and service development, and increasingly integrate such a regional dimension into their technical assistance delivery.

Ultimately, the contribution of a quality infrastructure and its services to regulatory authorities, private sector and consumers has to be seen in the wider context of an enabling business environment, be this national, regional or international. Only a good integration of quality infrastructure into a business enabling environment will allow private sector to prosper, to be competitive and to generate and maintain employment opportunities in the spirit of an inclusive and sustainable economic development.

Definition of Terms Relating to the Quality Infrastructure

The following are definitions of terms utilised throughout the document, together with their source if relevant:

Accreditation. Third-party issue of a statement, based on a decision following review, that fulfilment of specified requirements related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks, has been demonstrated. [*ISO/IEC 17000:2004*]

Calibration. Operation that, under specified conditions, in a first step establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. [*OIML V2-200:2007*]

Certification. Third-party issue of a statement, based on a decision following review, that fulfilment of specified requirements related to products, processes, systems or persons has been demonstrated. [*ISO/IEC 17000:2004*]

Conformity assessment. Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. [*ISO/IEC 17000:2004*]

Conformity assessment procedures. Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.
Explanatory note
Conformity assessment procedures include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations. [*WTO TBT Agreement*]

Inspection. Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements. [*ISO/IEC 17000:2004*]

Mandatory standard. A standard the application of which is made compulsory by virtue of a general law or exclusive reference in a regulation [*ISO/IEC Guide 2:2004*].

Metrology. Science of measurement and its application. [*OIML V2-200:2007*]

Peer Assessment. Assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group. [*ISO/IEC 17000:2004*]

Quality Infrastructure. The totality of the institutional framework (public or private) required to establish and implement standardisation, metrology (scientific, industrial and legal), accreditation and conformity assessment services (inspection, testing and product- and system certification) necessary to provide acceptable evidence that products and services meet defined requirements, be it demanded by authorities (technical regulation) or the marketplace (contractually or inferred).

Quality management. Coordinated activities to direct and control an organisation with regard to quality.

Standard. Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. [*ISO/IEC Guide 2:2004*]

Standard. Document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. [*WTO TBT Agreement*]

Technical Regulation. Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. [*WTO TBT Agreement*]

Verification. Provision of objective evidence that a given measuring system fulfils specified legal requirements. [*OIML V2-200:2007*]

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