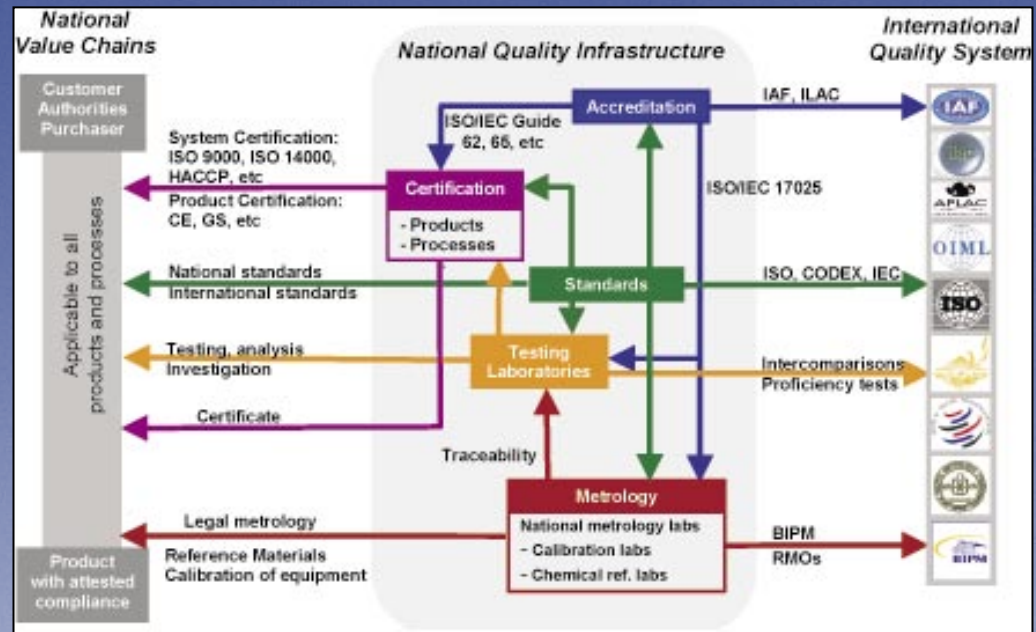




# Innovations in Export Strategy

*A strategic approach to the quality assurance challenge*







**International Trade Centre**

**Executive Forum**



UNCTAD CNUCED



WTO OMC

*Innovations in  
Export Strategy*

*A strategic approach to  
the quality assurance challenge*

Geneva 2005

## ABSTRACT FOR TRADE INFORMATION SERVICES

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Paper dealing with quality infrastructure issues – defines the concept of quality infrastructure; addresses key challenges related to development of a successful quality infrastructure; outlines a practical, structured approach to establishing an export-oriented quality infrastructure, tailored to specific circumstances; presents experience of selected countries in their innovative strategic approach to quality assurance; includes bibliography (p. 85).

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The consultation was conceptualized and managed by Natascha Weisert of the ITC Executive Forum Team.

This paper was edited by Alison Southby. Layout was done by Carmelita Endaya.



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## Note

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Unless otherwise specified, all references to dollars (\$) are to United States dollars. The term ‘billion’ denotes 1 thousand million.

The following abbreviations are used:

ACP	Asian, Caribbean and Pacific States
BIPM	Bureau international des poids et mesures
BRC	British Retail Council
CAC	Codex Alimentarius Commission
CARICOM	Caribbean Community and Common Market
CEHI	Caribbean Environmental Health Institute
CSA	Canadian Standards Association
DfID	United Kingdom Department for International Development
CIPM	Comité internationale des poids et mesures
DSM	Department of Standards Malaysia
EA	European co-operation for Accreditation
EAC	East African Community
EC	European Commission
EurepGAP	Euro-Retailer Produce Working Group – Good Agricultural Practices
EUROMET	European Collaboration in Measurement Standards
FAO	Food and Agricultural Organization of the United Nations
FSC	Forest Stewardship Council
GATS	General Agreement on Trade in Services
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit GmbH
HACCP	Hazard analysis critical control point
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ILO	International Labour Organization
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
IT	Information technology
ITC	International Trade Centre
ITU	International Telecommunication Union
MLA	Multilateral recognition arrangement

MoU	Memorandum of understanding
MRA	Mutual recognition agreement
MSTQ	Metrology, standards, testing and quality assurance
NMI	National metrology institute
NML	National Metrology Laboratory (South Africa)
NSB	National standards body
OIE	Office international des epizooties (World Organisation for Animal Health)
OIML	International Organization of Legal Metrology
PTB	Physikalisch-Technische Bundesanstalt (Germany)
SABS	South African Bureau of Standards
SADC	Southern African Development Community
SANAS	South African National Accreditation System
SCAM	Standards, certification, accreditation and metrology
Sida	Swedish International Development Cooperation Agency
SIRIM	Standards and Industrial Research Institute of Malaysia
SMEs	Small and medium-sized enterprises
SPS	Sanitary and phytosanitary (measures)
SQAM	Standards, quality assurance, accreditation and metrology
StanSA	Standards South Africa
STDF	Standards and Trade Development Facility
TBT	Technical barriers to trade
TQM	Total quality management
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
WHO	World Health Organization
WTO	World Trade Organization

## Introduction

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While tariff barriers have gradually come down, non-tariff barriers in the form of quality requirements (both official/mandatory and commercial/voluntary) increasingly affect the ability of developing countries and transition economies to compete in the global market. Nowadays, product quality and the capacity to confirm that required standards are being met largely determine a country's export performance. At the same time, quality and confirmation of compliance are the two areas where developing countries and transition economies are weakest.

Given their limited resources, the challenge for strategy-makers in these countries is to find the best approach to quality assurance through the creation of an appropriate infrastructure.

To explore how best to approach these challenges, ITC's Executive Forum organized the discussion 'A Strategic Approach to the Quality Assurance Challenge' under its 2005 Consultative Cycle on Innovations in Export Strategy. The specific objectives of this discussion were to:

- ❑ Provide a forum for strategy-makers and decision-makers to share experiences and lessons learned, and to discuss common challenges and policy implications with regard to developing an adequate quality infrastructure in developing countries and transition economies;
- ❑ Enable participants to understand the elements of, and programmes crucial to, an export-oriented quality infrastructure, and to discuss and debate best practice cases as well as emerging issues in the quality realm; and
- ❑ Publish a conclusion paper that, building on the consultation discussions, would provide a practical, structured approach to establishing an appropriate, export-oriented national quality infrastructure.

The consultation consisted of a preparatory e-discussion on the topic, conducted during June 2005, and the 27 to 30 June debate among participants from various developing and developed countries and facilitators in Shah Alam, Malaysia.

*'New standards coming up put a lot of constraints on developing countries and transition economies. We have to prepare ourselves to meet all the requirements by aiming to develop new capabilities and training human resources to the extent possible.'*

Khalida Mustafa, Principal Consultant, SIRIM Berhad, Malaysia

The documentation supporting the consultation included a number of ITC pre-discussion papers, and a variety of papers provided by members of the Executive Forum network. All can be accessed through the Executive Forum website dedicated to the Malaysia consultation ([www.intracen.org/execforum/ef2005/quality\\_assurance\\_challenge.htm](http://www.intracen.org/execforum/ef2005/quality_assurance_challenge.htm)).

## Purpose of this conclusion paper

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With the aim of providing a practical approach to setting up an appropriate quality infrastructure in developing countries, and based on the salient points raised during the consultation, this conclusion paper is structured in four parts.

- ❑ The first part provides an overview defining a quality infrastructure for better understanding of the topic. Rather than repeating the extensive and sometimes conflicting literature on the topic, it focuses on providing a brief summary of a quality infrastructure as presented graphically in a number of papers and the subsequent understanding generated during the consultations in Shah Alam.
- ❑ The second part of the paper addresses the key challenges related to the development of a successful quality infrastructure. The objective is to alert policy-makers and decision-makers from the public and private sectors in developing countries to these challenges, and to assist them in discussing and finding custom-tailored solutions to the fundamental questions of how the quality infrastructure should be designed, and how public-private partnerships can most effectively establish and maintain this infrastructure in view of significant resource and capacity constraints.
- ❑ The third part presents emerging quality issues relating to conformity assessment, quality assurance in the services sector and security-related quality requirements, all of which are likely to have serious implications for the quality infrastructure in the near future.
- ❑ The final part outlines a practical, structured approach to establishing a quality infrastructure tailored to specific circumstances, i.e. one which supports a country's competitiveness and realization of its export potential in line with its needs and existing resources. Examples of innovative thinking and associated country experiences are also presented.

Establishing and maintaining a quality infrastructure is an expensive and long-term business. Developing countries experience significant resource constraints and thus often get frustrated when trying to emulate the quality infrastructure of developed economies. But this is not always necessary, nor is it even desirable. Instead, innovative and more affordable solutions have to be found.

This conclusion paper seeks to provide strategy-makers and decision-makers in developing countries and transition economies with a comprehensive overview of crucial quality infrastructure issues, and also seeks to assist in establishing an enabling national quality infrastructure. Yet standardization and other conformity assessment issues are evolving rapidly and will continue to challenge developed and developing countries alike.

*'While the price of your export is negotiable, its quality is not.'*

Henri Jean-Claude Gouthon, Entrepreneur, Benin

Ideally, the exchange of views and experiences on quality infrastructure design, development and maintenance, as an integral part of national export and import strategies, should continue through the Executive Forum and its members. It is through such ongoing dialogue that the old and established patterns can be challenged, and new and more effective or efficient ideas and 'best practices' can be generated and implemented for the benefit of all.



## Part 1

# Understanding the quality infrastructure

---

Standards, standardization and quality have been part of human society since ancient times.<sup>1</sup> Not only are they likely to stay, but experience also shows that they increasingly shape commercial prospects for developing and transition economies.

In one form or another, they have always underpinned trade and business. Standards support compatibility and can drive down costs through use of common parts, specifications and methods. They can create new industries and allow the potential of new technologies to be exploited. They are also crucial to realizing and maintaining market access.

Over the past decades, these concepts have gained in importance and have become subject to more and more scientific and technological scrutiny and definitions. At the same time, the business world and society are changing rapidly. Global trade means that many of today's products are built with components sourced from around the world, which must fit together and perform as expected. Product life cycles are becoming shorter and the pace of technological development is accelerating. Consumers are demanding ever-higher levels of safety, performance, reliability and sustainability. All of this has to be facilitated by standardization and an appropriate underlying institutional framework.

This does not happen by itself. At company, national, regional or international level, a whole host of organizations are involved in the process of developing standards and especially in the verification that standards have been implemented, that compatibility is being achieved. These organizations interlink in many ways, require funding and have to be given the appropriate authority.

This part of the report endeavours to provide insight into – to ‘unpack’ so to speak – a complex web of organizational structures and activities to facilitate a better understanding of the strategic decision-making processes described in later parts.

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<sup>1</sup> An early account dealing with sanctions that apply when standards were not upheld is found in *The Code of Hammurabi* of Babylon (2067 to 2025 BC), which promised death to builders of houses that collapse on their inhabitants. To ensure fair trade, religious writings such as the Bible and the Koran included references to measurement standards as early as 1500 BC.

## Basic definition

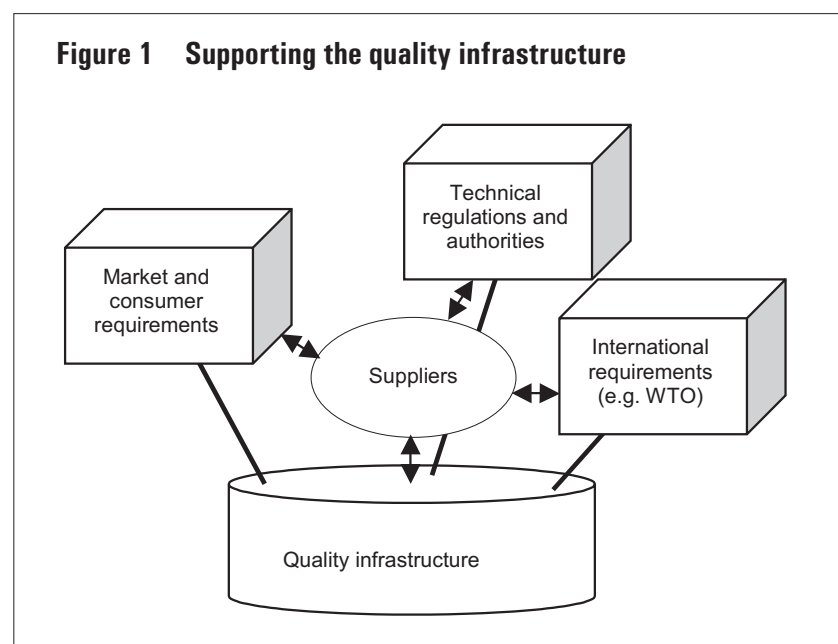
Acronyms such as SQAM, MSTQ and SCAM are used all around the world identifying various combinations and permutations of standards, metrology, quality assurance, accreditation, testing and certification. These acronyms add confusion, are limited in application or are restricted to a specific area of the world. Hence, it is much more useful to coin a new collective phrase that can be used more universally, namely 'quality infrastructure'.

*A quality infrastructure can be understood as the totality of the institutional framework, whether public or private, the output of which includes the process of formulating, issuing and implementing standards (i.e. to establish with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context) and the associated evidence of compliance (i.e. the relevant mix of inspection, testing, certification, metrology and accreditation), in order to improve the suitability of products, processes and services for their intended purposes, prevent barriers to trade and facilitate technological cooperation.<sup>2</sup>*

A useful picture of the tripartite arrangement that the quality infrastructure has to 'keep afloat' can be seen in figure 1. Three main constituents of the quality infrastructure are particularly crucial at the national and international level, namely the requirements of:

- ❑ Market and consumers;
- ❑ Regulatory authorities; and
- ❑ International or regional agreements (e.g. the WTO Agreements).

In the process of satisfying these three constituents, the quality infrastructure supports the activities of suppliers, and therefore facilitates trade.



<sup>2</sup> Derived from the definition of *Standardization* in ISO/IEC Guide 2:2004, International Organization for Standardization, Geneva.

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## Elements of a quality infrastructure

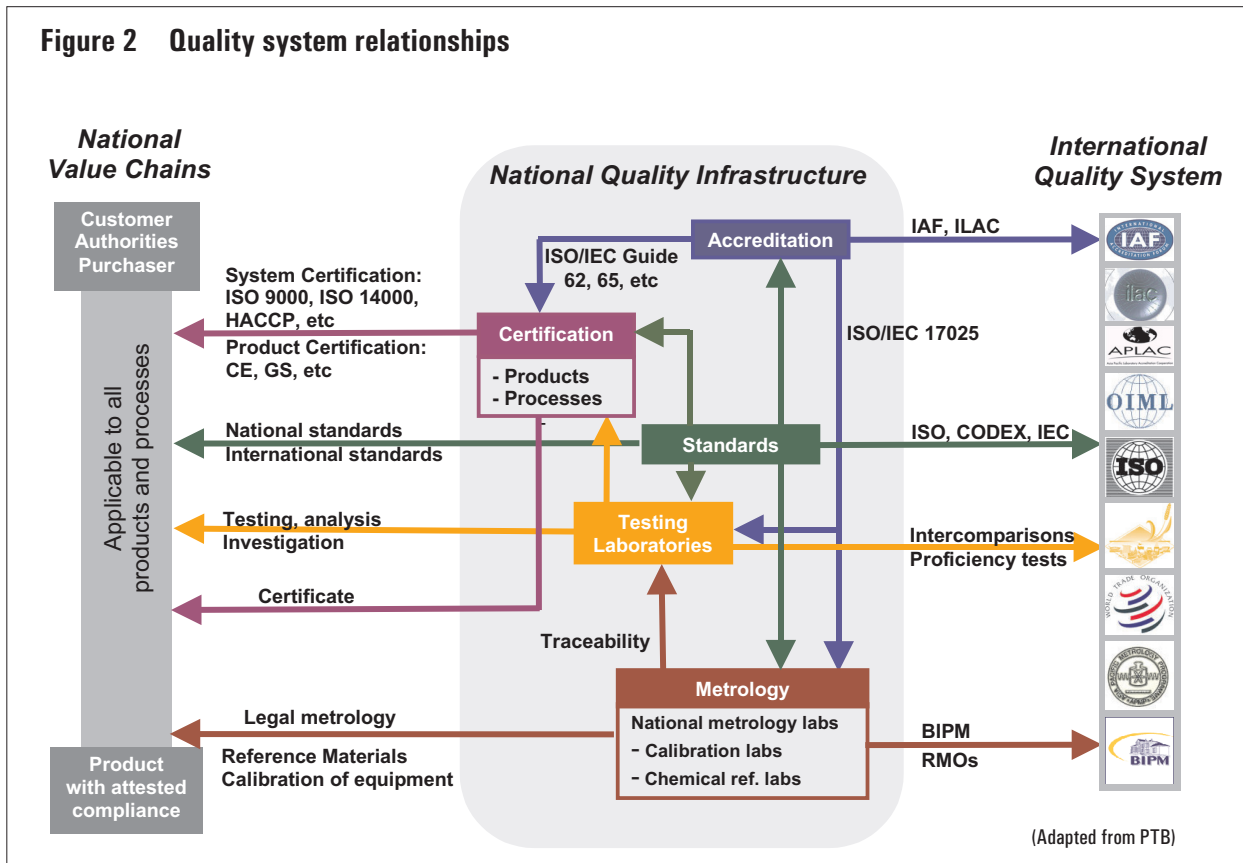
Suppliers and purchasers agree on the quality requirements a product or service needs to comply with before a successful trade transaction can be initiated. Once such an agreement has been reached, the purchaser needs to have the assurance that the product or service supplied will in fact meet the stated requirements. In more technical terms, the chain of evidence facilitating this exchange starts with standards, completed by evidence of compliance. But the evidence of compliance (conformity assessment) will be trusted only if the technical capability of those that provide such services is above reproach. Within the last century the output and services necessary to provide this have crystallized in developed economies, and the organizations providing them can be considered to make up the quality infrastructure. Therefore, the organizations that make up a quality infrastructure should individually or collectively provide the following output:

- ❑ **Standards** – the formal documentation containing the requirements that a product, process or service should comply with. Standards are considered essentially to be voluntary in nature. It is only once they are called up in a contract, for example, that compliance becomes a binding requirement.
- ❑ **Metrology** – the technology or science of measurement. Metrology can be subdivided into scientific metrology (the organization and development of the highest level of measurement standards), legal metrology (the accuracy of measurements where these have an influence on the transparency of economical transactions, health and safety) and industrial metrology (the adequate functioning of measurement instruments used in industry, production and testing).
- ❑ **Testing** – the determination of product characteristics against the requirements of the standard. Testing can vary from a non-destructive evaluation (e.g. X-ray or pressure testing after which the product can still be used) to a total destructive analysis (e.g. chemical, mechanical, physical or metallurgical tests after which the product can no longer be used), or be any combination thereof.
- ❑ **Accreditation** – the activity of providing independent attestation as to the competency of an individual or organization to provide specified services (e.g. testing, certification).
- ❑ **Certification** – the formal substantiation that a product, service, organization or individual meets the requirements of a standard.

These elements are all interrelated and to some extent all are required to provide the purchaser, user or authorities with the appropriate confidence that the product, process or service meets expectations. Figure 2 illustrates the relationships between the quality infrastructure organizations.

Everything starts with ‘Standards’ in the middle of figure 2. The standard contains the requirements for the product or service. The standard can be a national or international standard, or even a company-specific standard. Once the product has been manufactured it has to be tested by a testing laboratory. The certification organization assesses the supplier and the products or service and issues a certificate stating compliance with the standard. Through metrology the testing laboratory can ensure that its measuring equipment

Figure 2 Quality system relationships



meets standards, and through accreditation the technical competency of the laboratory and the certification organization is assessed and assured. At the international level various organizations (e.g. ISO, ILAC, IAF, OIML, BIPM) have evolved over the years, having as their members the national organizations. This is to foster a common understanding and mutual recognition of the outputs of the quality system throughout the world in these domains.

Given the complexity of organizations, linkages and national and international relationships decision-makers in developing countries have to make important strategic choices. Because of their limited resources, the following questions will have to be answered with a view to establishing a quality infrastructure conducive to maintaining and enhancing competitiveness:

- How are these various elements and organizations structured in the international domain?
- Is it essential to have all of these organizations in a developing country, or are some more important than others?
- Which ones should be established first, and can some be established at regional level?
- Which type of organizational structure is best suited to provide the various outputs? Should the organization be in the public domain? Or could private organizations be used?
- Who should fund such organizations, the State or industry or both?

- ❑ How can developing countries ensure that information on quality requirements is promptly and regularly received and disseminated?
- ❑ How can compliance be confirmed and enabled? What are the key issues to consider here and what approaches and programmes will be most useful in a developing country context?
- ❑ Which activities need to be undertaken to ensure that the output of the quality infrastructure at national level will be acceptable to trading partners abroad?

The remainder of part one, and the second and third parts of this conclusion paper seek to provide answers to these questions, drawing on the material provided during the consultation and other useful, practical examples from the developing world. The final part then presents a practical approach to embarking on a comprehensive review and reform of the quality infrastructure with a view to reinforcing and enhancing competitiveness.

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## Quality infrastructure organizations

The organizations that make up a quality infrastructure can be public or private organizations deriving their income from services rendered to authorities or industry, or they can be funded by the State. Anecdotal evidence from many developed and developing countries, as well as surveys of international organizations, provides an idea as to the most effective and efficient types of organizational structures.

### Standards

Standards are usually developed and published under the auspices of a *national standards body* (NSB) in accordance with requirements detailed in the WTO Agreement on Technical Barriers to Trade (TBT Agreement)<sup>3</sup> and in the Directives of ISO and IEC.<sup>4</sup> At the international level, a vast number of bodies (including ISO, IEC, CAC and ITU) deal with standards in a variety of sectors. Various types of memberships in these international standards bodies are available to NSBs. Usually only full membership entitles the NSB to participate fully in standards development activities.

A 2003 survey of ISO<sup>5</sup> indicated that more than 83% of its member bodies are government or semi-government organizations. The same survey also showed that just under 30% are 100% funded by government, whereas only 28% derive less than 20% of their funding from government. This indicates that:

- ❑ For an NSB to have the required authority and status in industry and society, it invariably has to be a government organization of some sort; and
- ❑ Funding for an effective NSB has to be a long-term commitment for the government, and hence is a strategic decision of note, even more so in

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3 **WTO TBT Agreement, Annex 3: Code of Good Practice for the Preparation, Adoption and Application of Standards.** World Trade Organization, Geneva.

4 **ISO/IEC Directives – Parts 1, 2 and 3.** International Organization for Standardization, Geneva and International Electrotechnical Commission, Geneva.

5 **ISO Members.** International Organization for Standardization, Geneva, 2003, ISBN 92-67-01384-X.

developing countries. Over and above the operating costs, membership fees of the appropriate international and regional organizations and the cost of participation in their activities constitute a major portion of the costs for smaller NSBs.

## Metrology

A *national metrology institute* (NMI) is responsible for ensuring that national measurement standards are maintained at certain accuracy levels, traceable to international standards, and address the needs of industry and the authorities of the country in question. The NMI is also responsible for ensuring that the national measurement standards are appropriately diffused into industry.

*‘Setting up an adequate metrology infrastructure is very complicated, but it has to be in place. In Uganda, for example, if we send off 10 kilos of a product and the importer claims he only received 9 kilos, what are we to do?’*

Umran Kaggwa, Agribusiness Management Associates Ltd, Uganda

NMIs are usually government or semi-government organizations. Most NMIs therefore obtain the bulk of their funding from government sources. This would indicate that appropriate long-term funding arrangements have to be in place. As is the case for NSBs, membership fees and active participation in the activities of international and regional metrology organizations constitute a major part of an NMI’s costs, especially for smaller NMIs, but are a necessary expense if their effectiveness is not to be seriously curtailed.

The major international metrology organizations are BIPM (scientific metrology) and OIML (legal metrology). BIPM is the permanent scientific institute of the Convention du mètre (Convention of the Metre). The highest decision-making body of the Convention of the Metre is CGPM, representing all the convention signatories (currently 48 countries). OIML is an intergovernmental treaty organization with 57 participating member countries and 48 corresponding members (observers).

CGPM and BIPM together ensure that an international, harmonized measurement system (the International System of Units – SI) is in place; without this system none of the other standardization or scientific activities and trade can take place. OIML develops international standards for measuring equipment used in trade and law enforcement, and manages an international certification system for such equipment. Both are therefore important for all countries, and hence have special programmes to support developing countries. Details can be found on their websites ([www.bipm.fr](http://www.bipm.fr) and [www.oiml.org](http://www.oiml.org)) or by contacting them directly.

## Testing

In the past, government laboratories were responsible for providing testing services especially to the authorities. This is changing rapidly as governments are reducing their involvement in the provision of services that can be effectively and efficiently provided by the private industry. Establishing and maintaining laboratories is a very expensive business, especially where the

technology is rapidly changing. Increasingly test laboratories need to provide independent evidence of their technical competence. This can be achieved initially through inter-laboratory comparisons but is better done by accreditation.

*'Testing can be very costly. In fact, it is sometimes less expensive to send products to foreign test labs than establishing your own national laboratories.'*

Rajinder Raj Sud, Senior General Manager,  
Standards Management Department, SIRIM Berhad, Malaysia

## Certification

Certification bodies provide an independent attestation that a product or a service complies with relevant standards. This has become mainly a commercial activity, even though both public and private organizations provide such services. In developing countries public organizations dominate initially, but they are soon eclipsed by private organizations (many of them with a multinational character) as the business becomes more lucrative. As is the case with test laboratories, certification bodies increasingly have to provide evidence of their competence, and hence also need to be accredited. There may still be a few isolated cases where governments maintain certification services in the national interest with no or little return on the investment.

## Accreditation

Accreditation organizations are recent phenomena driven by the need to provide independent evidence that conformity assessment service providers are technically competent. It would appear that the most cost-effective way for the industry and conformity assessment service providers in a developing country would be to establish one national accreditation body. However, this is a costly exercise and although accreditation services have to be paid for there is not enough business in most developing countries to maintain a national accreditation organization as a business proposition.

Therefore accreditation bodies are invariably government organizations in order to ensure that they have the appropriate status to be used by both the public and the private domain. The government should ensure that only one such body operates within a country as accreditation is seen as a non-competitive activity. Governments also initially have to provide the bulk of the funds for such organizations, and in developing countries will probably have to do so for a very long time because of the limited number of organizations that can potentially be accredited. Otherwise governments will have to make use of accreditation organizations in neighbouring economies. This becomes a strategic issue especially in the technical regulation domain.

At the international level, two organizations, IAF and ILAC, provide mechanisms for the peer evaluation and international recognition of accreditation organizations. This international recognition provides the mechanism through which the output of accredited service providers in the national quality infrastructure can be recognized abroad, thereby also facilitating the conclusion of recognition agreements between trading partners.

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## Technical regulations

Technical regulations are related to standards in the sense that they also determine the requirements that products and services have to comply with. The major difference, however, is that technical regulations are developed and implemented by authorities and enforced by law, whereas standards are voluntary in nature and generally enforceable only when called up in a contract between purchaser and supplier or referred in legislation. In addition, technical regulations also include the administrative procedures used by the authorities to enforce the requirements.

In an effective and efficient national set-up, the same quality infrastructure should be utilized to provide the required evidence that products and services meet the technical regulations as that used for requirements in the voluntary or commercial domain. It is a waste of scarce resources to try to separate voluntary/market conformity assessment services from those required for technical regulations. Regulatory authorities should not insist on testing and retesting products in their own laboratories, but should rather allow suppliers of products falling within the scope of technical regulations to choose between a number of laboratories and certification organizations in either the public or private domain. These laboratories and certification organizations should, however, be appropriately accredited to ensure their technical competency.

This sounds like a sensible approach, but recent reviews of technical regulation regimes in a number of economies reflect a different reality. Generally, due to a lack of a national policy framework for the development, implementation and maintenance of technical regulations, the systems are very fragmented. Each regulatory authority pursues policies and practices that it thinks best and, under the impression that it will lose control if other organizations get involved, endeavours to do everything itself. The result is a very fragmented approach at the national level that is not always effective, and mostly inefficient.

Technical regulations can very easily become major barriers to trade, and so the WTO TBT Agreement seeks to 'guide' the development and implementation of technical regulations in WTO Members by providing a universal set of rules. It is therefore important for developing country Members of WTO to make use of their right to attend the WTO TBT Committee meetings, which deal with the implementation of the TBT Agreement, and cover standards, technical regulations and conformity assessment issues. The TBT Committee is also facilitating programmes for developing countries to enhance their capabilities to meet their obligations under the TBT Agreement. Details can be found on the WTO website ([www.wto.org](http://www.wto.org)); the reports of the Triennial TBT Agreement Reviews are useful sources of information in this regard.

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## SPS measures

Just as some manufactured products can have a deleterious effect on the safety and health of society should they fail, so also can the introduction of pesticides, alien plant material, diseases, foreign bacteria and the like endanger indigenous plants and animals, and human health. Governments therefore implement measures to safeguard their plant and animal kingdom as well as human health against such calamities. These sorts of measures are generally known as sanitary and phytosanitary (SPS) measures.



In the case of SPS measures it is even more important that a proper import regime is in place. Unlike TBT, where the link between an import and export regime is slightly tenuous and the one can exist without the other, there is a definite link between import and export regimes in the SPS domain. Food and related exports can be very badly affected by the importation of products that have a harmful effect on indigenous plants and animals, the source of a country's food exports.

*'SPS measures can take many forms, such as imposing specific product or process criteria, requiring products to come from disease-free areas, setting of permissible maximum levels of pesticide residues, etc. All these measures must be based on international standards, guidelines and recommendations whenever possible.'*

K. Palasuberniam, Assistant Director, Export and Certification Section,  
Crop Protection and Plant Quarantine Division,  
Department of Agriculture, Malaysia

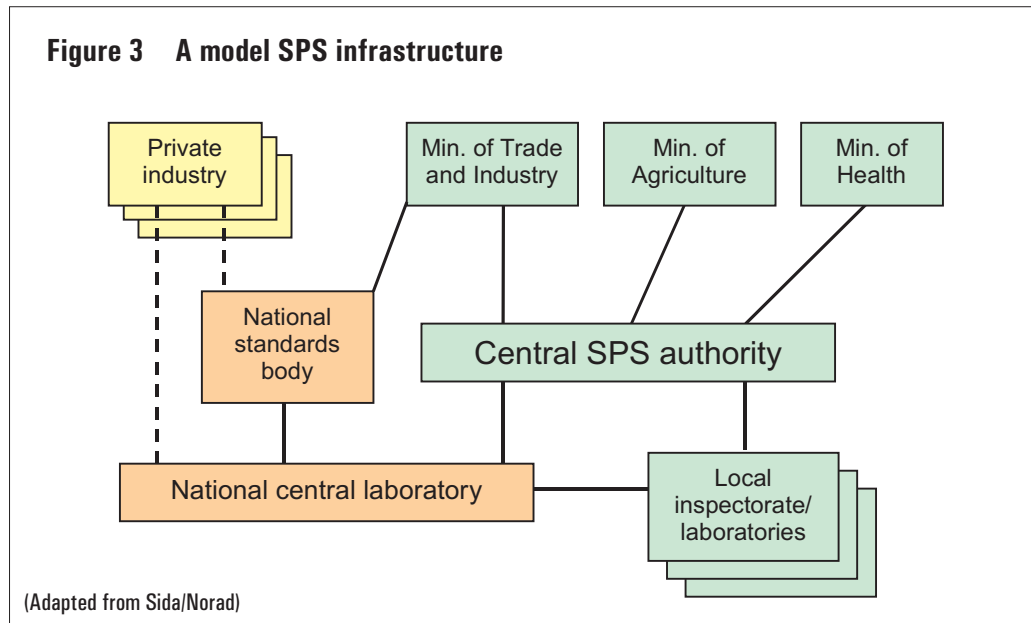
As is the case for technical regulations, it makes good economic sense to use the same quality infrastructure established for the voluntary domain (standards, metrology, accreditation, testing, etc.) for the SPS measures. This calls for a holistic approach that will be only followed if a policy and strategy have been agreed to at a high political level to be implemented by the relevant organizations. Developing countries with limited resources simply cannot afford to have separate systems for the voluntary domain and the technical regulation and SPS domains.

*'Although Malaysian products are currently exported to several countries, SPS measures still create difficulties when it comes to penetrating international markets.'*

K. Palasuberniam, Assistant Director, Export and Certification Section,  
Crop Protection and Plant Quarantine Division,  
Department of Agriculture, Malaysia

Establishing more than one accreditation body (e.g. one for technical regulation, one for SPS and one for the voluntary conformity assessment), is exactly the wrong thing to do. Once they have been established it is very difficult to merge them. Another mistake is for the national standards body to establish microbiology laboratories and the SPS authority to do the same. These approaches entail a significant waste of resources because of duplication and a lack of coordination. It would be much more effective to pool resources and, as noted in these examples, invest in *one* accreditation body or *one* set of laboratories.

A conceptual model of how an SPS system could be set up is shown in figure 3. An effective enforcement system is managed by a central SPS authority with overall responsibility for all the technical activities within the policy field. It coordinates the inputs from all the service providers (such as the NSB, the local laboratories and local inspectorates), which removes the need for them to establish new laboratories, inspectorates, and so on. At the same time, the



central SPS authority should be able to facilitate the coordination of the policies and strategies that emanate from the three main ministries responsible for elements of the SPS domain (e.g. the Ministries of Trade and Industry, Agriculture and Health). Quite often a national central laboratory already exists; this would then also become part of the network of SPS organizations, and could then fulfil its role as reference laboratory much more constructively. All the laboratories and the inspection agencies should be accredited to ensure their continued technical competency if such a system is to operate effectively and efficiently.

## Organizational requirements of the quality infrastructure

The quality infrastructure can take on many organizational forms.<sup>6</sup> The international community does not really mind what it looks like provided it delivers the relevant services effectively and efficiently without conflicts of interest. Many functional models exist throughout the world; two typical ones are shown in figures 4 and 5, but even these can be found in many subtle variations.

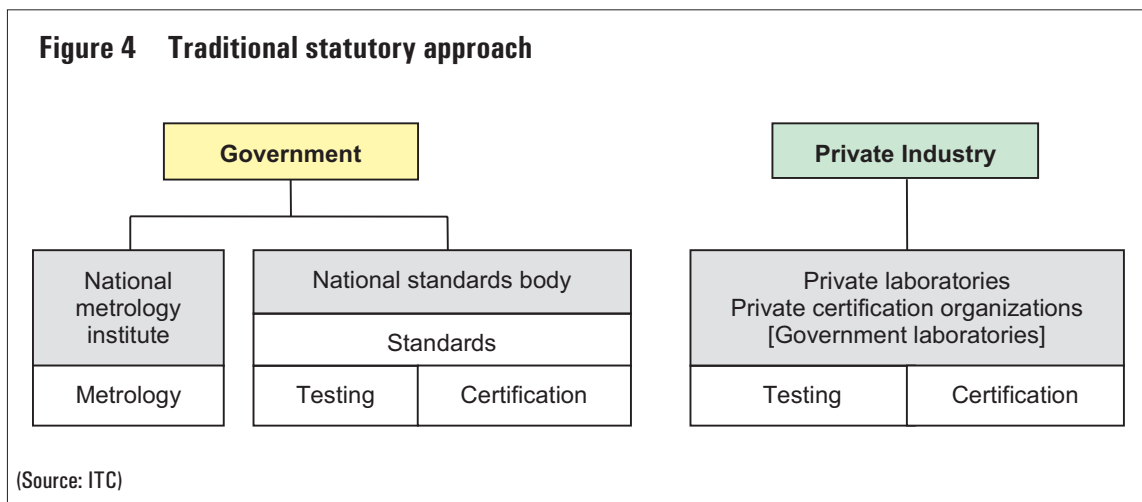
The first version, the traditional statutory approach, is encountered in many developing countries. This is the result of a belief that it is one of the most efficient approaches for developing countries to ensure optimal use of scarce resources. It is also an approach long favoured by the development agencies that helped developing countries establish a national quality infrastructure. It is based on the approach that emerged in the United Kingdom in the first half of the twentieth century.

<sup>6</sup> Road Map for Quality: Guidelines for the Review of the Standardization, Quality Management, Accreditation and Metrology Infrastructure at National Level (ITC, Geneva, Doc. No. BAS-04-19.E) provides background material and in-depth discussions on this topic.

The second version, the national quality mechanism, is a more modern approach that limits the operational involvement of government to the necessary, and facilitates public–private partnerships while at the same time providing a mechanism for government to guide policy and strategies to a large extent.

## Traditional statutory approach

In this approach, the national metrology institute and the national standards body (NSB) report to the government, usually the Ministry of Trade and Industry or a similar ministry. The Ministry (or the Minister) appoints the boards or councils of these institutions, and a large portion of the funding comes from government. In many cases the NSB may also be responsible for metrology, so one organization does all. Private industry and other ministries manage their own laboratories, independently of those from the NSB.



In this set-up, the NSB is often also responsible for the administration or implementation of compulsory standards. Advantages and issues relating to this type of quality infrastructure include the following:

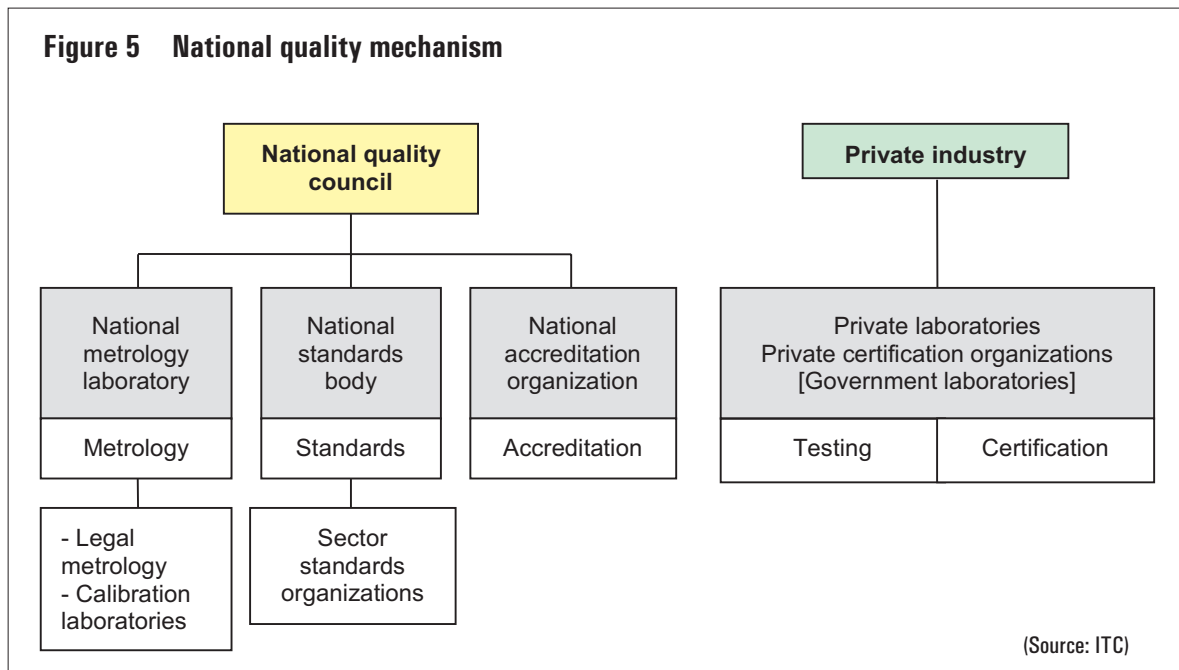
- Administrative and management overheads and facilities for the various activities can be shared;
- Long-term funding arrangements are influenced by the vagaries of state finances, and hence are not always secure enough to facilitate appropriate planning and development, or effective involvement in international and regional activities;
- Government can influence the strategy and business planning of the institutions quite effectively;
- Due to the multidisciplinary nature of the organization, one or more activities can dominate to the detriment of the others depending on the ‘comfort zone’ of top management;
- Industry does not always have an appropriate say in the strategies and business planning of the institutions;

- ❑ Due to the fact that the institutions are government organizations (especially when responsible for compulsory standards), customer focus and care and prompt service delivery suffers;
- ❑ The institutions are perceived as the ‘unwelcome policemen’ over industry rather than the support structure they should be; and
- ❑ The development of standards and especially compulsory standards takes the preferences of the organization into account rather than address national needs.

It is difficult to include accreditation in this type of structure, without creating massive conflicts of interest, especially if accreditation services are to be provided by the National Standards Body.

### National quality mechanism

Because of the difficulties encountered with other models, and to provide for positive private/public partnerships, the national quality mechanism type of approach is slowly emerging as a viable alternative, for developed and developing countries alike.



In this model, the main ministry responsible for the quality infrastructure (usually Trade and Industry) sets up and funds the standards development, metrology and accreditation functions. These functions cannot be established by private industry in any effective way. On the other hand, the national quality council is representative of both the relevant public and private domain. In its purest form it would act as a forum where strategies and policies can be debated and consensus reached. It should not act as a board or council for the institutions. That should be left to a much smaller board or council with more business- or finance-oriented individuals as members.

The actual conformity assessment service delivery is left to private industry that is appropriately accredited to ensure continuing technical competency. In developing countries, government may have to set up the laboratories initially, with the ultimate objective that they should become commercial entities. Advantages and issues for this type of structure include the following:

- ❑ A clear distinction exists between the state-supported or state-empowered activities (standards, metrology and accreditation) and those that can be commercially provided (testing and certification);
- ❑ Suppliers have a choice of conformity service providers;
- ❑ The structure does not contain inherent conflicts of interest;
- ❑ Each organization can focus more effectively on its specific area of work;
- ❑ Operational and management overheads, as well as staffing and facilities, can be outside the reach of many developing countries;
- ❑ Private industry and society can have a meaningful involvement in the development of strategies and policies; and
- ❑ The structure is generally representative of the established international organizations in this domain.

## Conclusion

Both models include public and private organizations. Some of the services are the sole domain of statutory or government bodies, whereas some services are provided by both the statutory bodies and private industry in competition, and sometimes private industry has taken over the services provision. This is a very complex issue, and there is no single way that can be considered a definitive model.

Given this complexity and the absence of a single model structure, policy-makers and strategy-makers at government level need to carefully assess what quality infrastructure would be the most appropriate for their country. This will not necessarily be easy and a number of important challenges have to be overcome. Part two presents these challenges and part four provides practical examples of how selected developing countries have dealt with them. Upgrading the national quality infrastructure with a view to maintaining and enhancing competitiveness will also have to include a comprehensive assessment of the current organizational structure, the commercial priorities and the associated quality infrastructure needs, and the financial, institutional and human resources available – a practical, structured approach to which is provided in part four.

## Part 2

# Developing a quality infrastructure – key challenges for developing countries

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Quality requirements are increasingly shaping commercial prospects for developing countries and transition economies at the same time as they are becoming ever more complex. In line with rapid development of products and services technology, technical regulations (the TBT domain) have become moving goalposts. In the food area, new SPS requirements are virtually at the forefront of measurement technology.

*'I learned a lot about quality management during this consultation. Quality management clearly is a crucial determinant of competitiveness.'*

Syviengxay Oraboune, Deputy Chief,  
Committee for Planning and Investment, National Economic  
Research Institute, Lao People's Democratic Republic

Over and above the regulatory requirements that legitimately deal with health and safety, additional quality requirements are imposed, driven by major purchasers,<sup>7</sup> selected conformity assessment service providers, and more and more sophisticated consumer preferences or pressure groups.<sup>8</sup> Developing country suppliers are compelled to comply with all these requirements, regulatory or market-related, in order to secure business. Yet often the national quality infrastructure can neither keep track of the information about constantly emerging new requirements nor adequately support suppliers. Expensive foreign third party testing and certification has to be engaged with the result that products and services are no longer competitive. It is a vicious circle, and it is therefore not surprising that developing countries feel overwhelmed by the demands and conditions imposed on them and feel that they are being discriminated against.

Yet these requirements are a reality that can be ignored only at the cost of not being able to compete and to meaningfully participate in international trade. A concerted effort by public and private sector decision-makers in developing countries will be required to make effective use of the scarce resources available

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7 The British Retail Council (BRC) Standards (based on HACCP concepts) and the integrated crop management certification based on the EurepGAP Standards in Europe are noteworthy examples.

8 These include requirements such as ISO 9001, ISO 14001, ISO 22000, SA 8000, and OHSAS 18001, some of which are international standards, others not. Management system-related requirements are also increasingly mandated, such as HACCP, traceability, terrorism-related safety, etc. Part three provides more details.

and to channel these to adequately support their industries (including the SME sector) to meet globally demanded quality requirements.<sup>9</sup> If there is no strategic plan, a loss of competitiveness and a waste of resources are the likely results.

To successfully engage in such an effort, policy-makers and decision-makers from both the public and private sectors will have to address the fundamental questions of how their quality infrastructure should be designed. As already indicated in part one, however, there is no widely accepted model for setting up an efficient and effective national quality infrastructure. Developing an adequate national quality infrastructure therefore poses a number of important challenges.

*‘The absence of a well-established quality infrastructure puts developing country exporters in a “no win” situation.’*

Parama Iswara Subramaniam, Senior Manager, Quality Management Systems Certification, SIRIM QAS International Sdn Bhd, Malaysia

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## Quality infrastructure – set-up and organizational challenges

The challenge faced in establishing an appropriate quality infrastructure depends, above all, on whether some elements of a quality infrastructure already exist, or whether it has to be established from scratch. The former situation is probably a bit more difficult, because the old system is usually well entrenched and has to be undone before a new one can be established. In either of the two scenarios, the following considerations will be important.

### A holistic approach

Anecdotal evidence from around the world indicates that some of the elements of a quality infrastructure are so fundamental that establishing them is the first priority. This would include establishing the national measurement standards and legal metrology based on the precise measurement needs of industry and the authorities. The next priority would be to establish an operational national standards body in line with the needs of industry and the authorities. Both of these will have to be funded, at least to a large extent, by government.

Laboratories and then the certification activities should be established next. Certification could also be established at the same time as the laboratories. Only then would accreditation at the national level be attended to. Whereas testing and certification can become a totally commercial activity, accreditation would have to be funded largely by government in developing countries. At the same time, the involvement of the quality infrastructure in technical regulation implementation should be facilitated.

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<sup>9</sup> Developing an adequate quality infrastructure in developing countries will also allow them to deal more effectively with the dumping of sub-standard products, which often happens with less than effective technical regulation regimes in place. Resources invested in the quality infrastructure should therefore also deal with the quality of imported products, with the aim of creating a level playing field.

This state of affairs does, however, provide manoeuvring space for developing countries or transition economies to establish a quality infrastructure that is appropriate for their needs, and one which they can afford. Each economy is unique in its own right, and *one size does not need to fit all*. The temptation is to emulate developed countries. They have had the privilege of a century of development which cannot be replicated in a short time, but also carry a tremendous amount of historical baggage that renders their systems often very clumsy and inefficient. Developing countries can approach the establishment or the review of their quality infrastructure from a much more pragmatic perspective.

### **Challenge**

*For a national quality infrastructure to be effective, the involvement of the authorities is crucial, as is a holistic and strategic approach. The following challenges have to be dealt with to ensure the establishment of an adequate quality infrastructure:*

- ❑ *A holistic, strategic policy regarding the quality system has to be established at national level linking with other policies such as trade, environment and health;*
- ❑ *The articulated standards, inspection, testing and certification needs of industry and authorities have to be met;*
- ❑ *The development, implementation and maintenance of technical regulations should be based on standards, and appropriate use should be made by the regulatory authorities of the metrology, accreditation, testing and certification service providers;*
- ❑ *Funding by government has to be secured so that the long-term viability is assured;*
- ❑ *The system must be subject to a review mechanism (i.e. accreditation) that establishes the technical competency of all the institutions to the satisfaction of local authorities, and foreign authorities and the markets abroad; and*
- ❑ *Conformity assessment services for locally produced products and services for the local market and exports, as well as imported products, should be provided on a 'user pays' basis in an affordable and non-discriminatory manner.*

All of the above seems to be common sense, but the reality is that organizations within the quality infrastructure are often developed in splendid isolation, because they report to different Ministries, are the recipients of development aid with a specific objective, act independently or because there is no Ministry prepared to take the lead in developing a holistic national approach. The result is a fragmented and less than optimal national quality infrastructure.

## **Governance**

Organizations require proper governance. Because the organizations in the national quality infrastructure are often government or statutory organizations, the way they are governed is prescribed by law. Notwithstanding such legal requirements, governance prerequisites are twofold:

- ❑ The need for strong accountability to a wide range of national stakeholders in both the public sector (ministries and regulatory authorities) and private sector (industry associations, individual industries, SMEs, etc.); and



- ❑ The need for strong accountability to the major ‘shareholder’ of the organizations (the Ministry of Trade and Industry or similar) for the effective and efficient business management of the government-funded and ‘commercial’ activities of the organizations.

In practice it is extremely difficult to have a single governing body that fulfils both roles. Reviews in a number of countries of the role and composition of the current councils or boards as defined in the relevant legislation (e.g. standards acts) indicate that an attempt has been made to define the role of looking after the interest of various stakeholders from a ‘representation’ perspective. These acts however, are often less clear on the accountability of the council or board (and the CEO) as regards effective and efficient business management.

Good governance would be to have clear separation of accountability and responsibility from a ‘representation’ and ‘business’ perspective. This then allows for both ‘representation’ skills and ‘business’ skills to be embodied within the governing structures. It follows that two governance type bodies have to be established with different mandates and clearly articulated responsibilities.

### ***Governing council or board***

Fiduciary and other responsibility for the organization should be vested in a council or board as allowed for by the legal environment. While not being as aggressively commercial as the board of a private company, the council or board would still be expected to exercise sound strategic, financial and managerial responsibility within the framework of the national interest. The recommendations from the national quality forum (see below) would have to be given a high and demonstrable priority. Among other issues, the council should focus on:

- ❑ The national interest and social responsibilities (standards development, standards information, standards liaison, etc.);
- ❑ Facilitating and encouraging the development of commercial, value-added services;
- ❑ Receiving status reports and financial statements; and
- ❑ Monitoring and facilitating regional and international involvement.

Council or board members should be selected from stakeholder groups, with a strong emphasis on individuals with demonstrated business acumen. The number of members could be between seven and ten. The CEO of the organization should be a full member of the council or board.

### ***National quality forum***

A national quality forum or similar (depending on the custom and practice of the country) with wide representation of all stakeholders should be formed; this will foster public–private partnerships. Ideally this forum should not take over the governance of the various institutions of the quality infrastructure, but be a sounding board for the authorities to find out what stakeholders’ needs are, and for industry to sensitize the authorities as to the real issues regarding quality that have to be addressed at national level. Typical examples can be found in both developed and developing countries, including Costa Rica and the United Kingdom.

### **Challenge**

*Within the constraints of national custom, practice and legislation, the governance of the various organizations of the quality infrastructure (i.e. government or statutory bodies) has to be set up in such a way that it provides for:*

- ❑ *Strong accountability to a wide range of national stakeholders in both the public sector (ministries and regulatory authorities) and private sector (industry associations, individual industries, SMEs, etc.); and*
- ❑ *Strong accountability to the major ‘shareholder’ of the organizations (the Ministry of Trade and Industry or similar) for the effective and efficient business management of the government-funded and ‘commercial’ activities of the organizations.*

*Note: Private companies providing conformity assessment services will be governed by normal commercial laws and parameters.*

## **Conflicts of interest**

One of the major issues in establishing a quality infrastructure relates to conflicts of interest. Perceived or real, they can become a major stumbling block to the ultimate acceptance of the structure and the services it provides to industry or trading partners. They include:

- ❑ The regulatory authorities should not manage the laboratories for the testing of products falling within the scope of technical regulations for which they are responsible. Otherwise they can easily be accused of testing products only to secure an appropriate level of income for the organization, rather than testing when it is really necessary.
- ❑ The organization providing testing services (typically the national standards body) should not be involved in accrediting other laboratories, as this would obviously constitute a conflict of interest.
- ❑ Foreign products should be treated the same as local products, i.e. the amount of testing and the costs for testing and certification should be comparable.

### **Challenge**

*Establishing one organization that provides all the services required of a quality infrastructure is an attractive way forward for developing countries faced with severe constraints. Such an approach, however, results in major conflicts of interest, which lead to non-acceptance of the system and its services. Hence the appropriate structures should be established to negate any real or perceived conflicts of interest:*

- ❑ *Regulatory authorities should not control the laboratories testing products falling within the scope of compulsory standards;*
- ❑ *Organizations that manage laboratories or provide certification services cannot be made responsible for accreditation services; and*
- ❑ *Suppliers should have a choice of conformity service providers, especially in the case of products or services falling within the scope of technical regulations.*

- ❑ Suppliers should have a choice of conformity assessment service providers. If only one testing laboratory or certification organization is acceptable to the authorities or the major purchasers, then market forces cannot be brought to bear to ensure reasonable pricing policies for the conformity assessment services.

## Funding

The availability of appropriate and adequate funds to establish and maintain the organizations that constitute the basic elements of a quality infrastructure (metrology, standards, accreditation and possibly selected testing and certification) is quite a challenge for developing countries. Governments have to deal with such a multitude of social issues that technical activities such as a quality infrastructure often come a poor second. The downside of such an approach, however, is that the export industry will be negatively affected and the safety and health of the society and the environment likewise. Examples of the costs of developing and implementing a quality system in the fish sector and the returns on the investment can be seen in appendices I and II.

*‘As regards metrology, we invested in instrumentation and have a very strong team. In the case of important exports, exporters have been ready to provide funds to set up the measurement infrastructure.’*

Prudence Asamoah-Bonti, Head of Unit,  
Standards Development, Ghana Standards Board

There is little chance that the industry will be able to fund these basic activities, so government has little choice but to fund them. The challenge is to separate the services that are:

- ❑ ‘Good for the country’ – in which case government has to fund them; and
- ❑ ‘User pays’ services – in which case they can be kick-started by government, but ultimately (and the sooner the better) they have to be funded by the clients that make use of them.

This means that any funds provided from state coffers need to be clearly allocated to specified activities, and proper account has to be given at the end of

### **Challenge**

*Long-term funding for the essential services is required for the quality infrastructure to operate successfully, as the industry normally cannot or does not fund these activities. The challenge therefore is to:*

- ❑ *Secure long-term government funds for the establishment and maintenance of standards, metrology and accreditation;*
- ❑ *Provide funds against predetermined budgets and agreed outputs; and*
- ❑ *Provide government funds for the establishment of commercial activities such as testing, calibration and certification but migrate as quickly as possible to a situation where these are funded from service fees.*

every financial year against the original budget. Providing a lump sum to such institutions without proper budgets and financial accountability will be a disservice to all.

On the other hand, the price for services (such as testing, certification or calibration) that can be provided on commercial basis should be market related and not controlled by government. Government price control removes the incentive for the organization to become commercially viable, and in the end is tantamount to government subsidy, because such prices are invariably below market levels. It also opens up the organization (and government) to criticism that it competes unfairly with private industry and will inhibit the establishment of a viable private testing and certification industry. Financial support to SMEs that cannot afford such services should be provided in another way.

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## International linkages

Because of the immense importance of quality infrastructure outputs in the context of international trade, national organizations and governments have established international organizations for the fundamental elements of a quality infrastructure. These include:

- ❑ International standards organizations, e.g. ISO, IEC, ITU, CAC;
- ❑ International metrology organizations, e.g. BIPM, OIML;
- ❑ International accreditation organizations, e.g. IAF, ILAC.

Quite a number of these are mirrored at the regional level, such as EU, SADC, ASEAN, MERCOSUR, EAC. Membership of these organizations is generally not free, and participation in the activities of such organizations (technical committees, general assembly, etc.) also requires appreciable funds. The question therefore is what does membership mean, and is it a requirement for the effective and efficient operation of the national quality infrastructure organizations in developing countries.

## Practical considerations

Membership of the various international and regional organizations mentioned above is important for developed and developing countries. Key considerations include:

- ❑ International standards are often protected by copyright (ISO and IEC standards in particular) and cannot be adopted as national standards without the required transfer of copyright. Once a national standards body becomes a full member, copyright is transferred; other levels of membership may impose severe limitations in this regard. Therefore, the level of membership is not only a question of cost, but also a strategic decision regarding the adoption of international standards as national standards.<sup>10</sup>
- ❑ Most developing countries are standard-takers rather than standard-makers. It is only a small number of highly industrialized countries that are involved in the real development work. Hence it can be argued that developing

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<sup>10</sup> Developing countries may adopt up to 200 IEC International Standards free of charge under IEC's Affiliate Country Programme. See [www.iec.ch](http://www.iec.ch).

countries need not be involved in the technical committees that develop the international standards. This is not necessarily true. In many cases the developing countries are the main suppliers of products for which the developed countries are developing the standards. If no input is received from developing countries then their industries may have to comply with standards that impose severe limitations or penalties. (See also ‘Standards development’ on pages 32–33.)

- ❑ Many of the international organizations have programmes for the development and support of organizations from developing countries, but these are obviously available only to member bodies. Examples include the Developing Country Programme of ISO, the Codex Alimentarius Trust Fund and the STDF programme.
- ❑ Some of the international bodies (e.g. OIML, IEC) have established product certification schemes, especially in technical regulation domains such as trade metrology, explosion proof equipment for use in fiery mines, electrical safety of household appliances and many more. As a member of these organizations, developing countries could use these schemes to ensure that such equipment sold in their own countries meets international standards, which would otherwise be more difficult.
- ❑ Membership of organizations and especially membership of multilateral recognition arrangements (MLA) provides evidence to the international markets and to regulatory authorities in other countries that the standards and certification activities in a developing country are on a par with international standards.

*‘With the requirements contained in the TBT and SPS agreements being the preferred choice for developing technical regulations, participation in international standards activities is no longer an option, but necessary to ensure long-term market success.’*

Rajinder Raj Sud, Senior General Manager,  
Standards Management Department, SIRIM Berhad, Malaysia

### **Challenge**

*Full membership of international organizations such as ISO and IEC is costly, as is meaningful participation in general assemblies and technical committees. On the other hand, lack of membership imposes severe penalties on developing countries in that they are on the receiving end of international standardization activities without being able to influence them. In addition, copyright issues may prevent developing countries from adopting international standards. Therefore the challenge is to:*

- ❑ *Select the appropriate international organizations for membership consistent with the trade, safety, health and environmental strategies of the country;*
- ❑ *Select the appropriate level of membership in order to gain the maximum benefits (especially copyright of international standards) for the country; and*
- ❑ *Secure appropriate long-term funds to ensure continued membership and relevant involvement in the activities of these international organizations.*

## Regionalization

### Practical considerations

To establish and maintain a national quality infrastructure is an expensive business and requires a long-term financial commitment from authorities and industry. Developing countries are particularly challenged with regard to the establishment of metrology institutions and testing laboratories. In the case of metrology it has been shown worldwide that without secured long-term government funding, such institutions cannot function effectively. Also, many developing country authorities are still of the opinion that national laboratories are required to protect the health and safety of society, and that private laboratories cannot be trusted.

*'A metrology infrastructure is very expensive and a regional approach can reduce those costs. The problem is that most countries think that metrology is a matter of sovereignty.'*

Juan María González Vásquez, SEYMA, Costa Rica

A regional approach therefore provides an interesting alternative, allowing countries to share resources, trained personnel and equipment. More recently, various regions have had discussions on establishing a regional accreditation body, including SADC, EAC, CARICOM and West Africa. There have also been initiatives to establish a 'centre of excellence' for specific testing services in a region, e.g. a packaging testing laboratory in one of the SADC member States for all to use, the Caribbean Environmental Health Institute (CEHI) in Saint Lucia providing advice and testing services on solid and liquid waste management, water quality and resource management, etc. for the CARICOM region.

### Political and other difficulties

Unfortunately regional institutions have found it very difficult to establish themselves, and even where they do exist, national authorities are very reluctant to make use of them. The SADC packaging laboratory never got off the ground, and CEHI is under-utilized and struggling financially. After some initial enthusiasm, the idea of an EAC accreditation organization has been superseded by the establishment of national bodies in two of the three EAC member States. The SADC regional accreditation body is facing some major issues:

- Whom will it be accountable to?
- Where will it be incorporated?
- Who will fund it during the four to eight years it needs to establish its international recognition?

In the meantime South Africa is providing the bulk of the accreditation services in the region through the South African National Accreditation System (SANAS). Another example is ICAITI (a regional organization with the objective of, *inter alia*, developing regional standards and providing means to ensure compliance with them) in Central America that was set up in the 1950s and eventually failed in the 1990s because of the lack of political support.

Hence, the biggest stumbling block for regionalization has proved to be at the political level. The appropriate MoUs or protocols are, as a result, either not properly thought through or established, or if established are not effective.

One of the main reasons for the political difficulties has to do with a perceived loss of control. This is quite understandable: for example, in the case of regulatory authorities some means of ‘control’ over conformity assessment service providers for the inspection, testing and certification of products or services falling within the scope of technical regulations is critical. Should the conformity assessment service provider be shown to be at fault, then the authorities would like to have legal recourse over it. This is not easy if the service provider is located in another country, even if it is a regional institution.

### ***Regional cooperation***

#### ***It works in both developed and developing countries***

1. Various national metrology institutes in Europe have established their measurement capability at a level appropriate for their respective industry needs. Some (e.g. Germany, the United Kingdom) are of necessity much more advanced; their measurement capability may be an order of magnitude better than the next (e.g. Italy, Greece). These capabilities have, however, been demonstrated and are clearly defined in the CIPM Mutual Recognition Arrangement database administrated by BIPM. Yet these institutes are all part of the European regional network (EA),<sup>11</sup> where they can usefully share information and resources in spite of the large differences in technical capability. They will never be at the same level, yet can still work together at the regional level.

2. Another example from the metrology domain is South Africa, which has a sophisticated metrological infrastructure that is participating in international comparisons in order to ensure that its national measurement standards and technical capability can be recognized at the international level. The South African National Metrology Laboratory then arranges the regional comparisons within SADC where some national metrology institutions (NMIs) are at a very low technological level. In this way the SADC country NMIs gain insight as to their compatibility with the international metrology environment, and their measurement capability can eventually be recognized through the CIPM Mutual Recognition Arrangement.

## **Practical regional structures**

It may therefore be more feasible and politically more acceptable to develop the national infrastructure first and get it to operate at<sup>12</sup> a reasonable level, and then link the national institutions in a network that can share experiences and limited resources such as equipment and personnel. The elements of the national infrastructure need not be at equal levels of development or even technological competence for an effective regional network to be established. Developing countries can participate in the CIPM Mutual Recognition Arrangement and have their calibration and measurement capabilities

11 European co-operation for Accreditation, Internet: [www.european-accreditation.org](http://www.european-accreditation.org).

12 A useful reference is the step-by-step approach provided in ‘Quality First’, chapter 9 of *Is Your Trade Support Network Working?* (the publication following Executive Forum 2001), which can be downloaded from [www.intracen.org/execforum/ef2001/publication.htm](http://www.intracen.org/execforum/ef2001/publication.htm).

published for parameters of importance to them, such as mass or volume. The technological level of the metrology infrastructure is not a barrier to participation. In fact, metrology is one area where no economy can afford not to participate in the international recognition systems, no matter how low level the technical capability might be. As recognition is driven by intergovernmental institutions, policy-makers have no choice but to provide the required means at national level to make it happen.

*‘Once your quality infrastructure is in place, you can go for mutual recognition agreements. A certain level of confidence among all the parties is necessary for them to be accepted, but, once accepted, they serve to enhance trust and capability.’*

Khalida Mustafa, Principal Consultant, SIRIM Berhad, Malaysia

Regional approaches should be strengthened once a national quality infrastructure has been established and the national sensitivities appeased. For example, the national quality infrastructure should facilitate the use of laboratories in neighbouring countries that are suitably accredited, especially where it cannot provide such services from within its own ranks.

A national accreditation organization in a developing country is unlikely to cover costs through accreditation fees because there is just not enough work. Many governments therefore are very reluctant to establish such an organization, understanding that it will be a constant drain on the government purse. Yet, from an international trade perspective they need one. One strategic option is to officially recognize an internationally recognized national accreditation organization in a neighbouring country, but with the understanding that it would use local auditors (obviously suitably trained and registered) for assessments. In this way local capacity is enhanced, costs for the organizations to be accredited are minimized and national sensitivities are dealt with to some extent.

*‘The priority should lie in establishing a basic level of a national quality infrastructure and to only then move to a network of regional contacts.’*

Juan María González Vásquez, SEYMA, Costa Rica

### ***International recognition of measurements – the CIPM Mutual Recognition Arrangement***

#### ***The case for participation***

*As a consequence of laboratory accreditation and international trade agreements, a transparent and reliable system had to be put in place with respect to the consistency of the national measurement standards of countries that serve as the basis for measurement traceability and calibrations. These considerations led to the creation of an international agreement under the umbrella of the Convention of the Metre. By 2005, this CIPM Mutual Recognition Arrangement (CIPM MRA) had been signed by 45 member States, 17 associates and 2 international organizations. ➡*





*The objectives of the CIPM MRA are:*

- ❑ *To establish the degree of equivalence of national measurement standards maintained by NMIs;*
- ❑ *To provide for the mutual recognition of calibration and measurement certificates issued by NMIs;*
- ❑ *Thereby to provide governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs.*

*The outcome of the CIPM MRA is published in the form of statements of the measurement capabilities of each NMI in a database maintained by BIPM. International recognition of claimed calibration and measurement capabilities (CMCs) of NMIs is conferred through publication of the capability in the MRA database, and is publicly available on the Internet ([www.bipm.fr](http://www.bipm.fr)). CMCs are only published after an extensive regional and international peer review process, which ensures:*

- ❑ *That the claims are consistent with the results of inter-laboratory comparisons between the NMIs; and*
- ❑ *That the NMI has an acceptable quality system (e.g. ISO/IEC 17025), or has been peer assessed to a standard at least equivalent to it, in place.*

### **Challenge**

*Establishing a quality infrastructure is an expensive business, especially in areas of fast moving technology such as testing, or high precision such as metrology. On the other hand it is useful from a political perspective if a national capability is available, even if only rudimentary. Hence the challenge for developing countries is to:*

- ❑ *Establish the elements of a quality infrastructure at a technological level appropriate to the needs of the industry and authorities;*
- ❑ *Gain relevant international recognition through the appropriate structures set up by the international bodies responsible for metrology and accreditation; and*
- ❑ *Establish a regional network encompassing national organizations that does not usurp the authority of the national level, but augments its capacity with much needed higher technical capability and personnel with more advanced training.*

*'Regional networks for establishing a quality infrastructure might be a very good alternative for cost-intensive elements, such as metrology.'*

Ulrich Diekmann, Physikalisch-Technische Bundesanstalt (PTB),  
Q.52 Technical Cooperation in Africa, Near-East and South-East Asia,  
Germany

## The information gap

In order to prepare for the export market, relevant and complete information is absolutely essential about both mandatory and voluntary requirements as well as consumer preferences. It is equally important to obtain advance information on a timely basis to improve products or services and to maintain market access or position, or even to protect a whole industry. The quality infrastructure should be enabled to make a useful contribution in this regard.

### *Information is crucial*

#### *Medical rubber gloves – an example from Malaysia*

*The issue.* Doctors in the United States of America and parts of Europe reported that some patients had died from allergic reactions to rubber gloves and at the same time complaints of allergy reactions from rubber gloves by medical staff were increasing. Malaysia is a major producer, with several factories and thousands of workers employed. Calls to restrict the use of rubber gloves or use alternative materials would have had a major influence on the local industry. The industry could basically collapse.

*The strategy.* Research quickly indicated that proteins in the latex rubber were producing these allergic reactions. Rubber gloves are made to Malaysian standards but the standards did not provide for these aspects. Malaysian industry was made aware of the problem and quickly initiated programmes to solve the problem of allergy in rubber gloves by reducing the proteins during processing. They were able to respond in a timely manner, thereby saving the industry on the basis of advance information.

(Adapted from SIRIM Berhad, Malaysia)

## Technical regulation and SPS information

A major challenge is that business, industry and especially SMEs seldom have or take the time to keep track of developments. In addition only the major organizations can afford an infrastructure that would be able to do so. Therefore, both public and private sector organizations and associations have to play a meaningful role in tracking, acquiring, reviewing and disseminating information relevant to the economic sectors of the country. Another major issue is to sift the masses of information, and distil only that which is of use to the industry. Developing countries in particular suffer from this information overload.

*'In Malaysia, we subscribed to the Canadian 'Export Alert' system in order to alert exporters and to allow them to take the appropriate actions in response. They really need to be aware of the changes.'*

Rajinder Raj Sud, Senior General Manager,  
Standards Management Department, SIRIM Berhad, Malaysia

In the public domain, national TBT and SPS enquiry points should track developments regarding technical regulations in target markets by systematically processing WTO notifications through an appropriate system such as the Canadian ‘Export Alert’,<sup>13</sup> Brazilian ‘Alerta Exportador’<sup>14</sup> or similar, or by using facilities offered by WTO for screening notifications of interest to developing countries. These early alert systems review all the notifications emanating from WTO, sift them and classify them, and then provide only the relevant information to specified industry sectors or organizations.

Because TBT enquiry points are often attached to the national standards body, the knowledge of the standards body regarding the industrial environment in the country should be used to evaluate this WTO information, which is often expressed in wording that is not easily assimilated by industry and definitely not by SMEs. This could initially be handled by standards information personnel after suitable training. Eventually dedicated personnel might be required as the export business of the country diversifies and grows. The same could apply to SPS enquiry points.

Other sources of TBT and SPS information can be found on the websites of major industrialized countries, the EU (<http://europa.eu.int>) and international organizations, such as FAO ([www.fao.int](http://www.fao.int)). One important source of SPS information is the International Portal on Food Safety, Animal and Plant Health ([www.ipfsaph.org](http://www.ipfsaph.org)).

## Market information

Within the private sector, information can be obtained in various ways, e.g. through sector associations, associations of manufacturers, federation of chambers of commerce and industry at regional and international level. The Internet is also a useful source of information. Trade commissions overseas could alert exporters to relevant changes in export markets. Modern technology (e.g. the Internet, e-mail) allows associations to establish a whole network of information sharing quite easily, without having to set up a massive administration. This is crucial especially for those products and services that are important to the export performance of the economy. It is very important to also discern trends and not just identify sporadic bits and pieces of information.

*‘A diagnostic study recently carried out in Kenya revealed that somehow the information was available, but not in a user-friendly format. Many people, for example, do not have access to the Internet and cannot receive information via e-mail.’*

Cosmas Kyengo, Adviser,  
Fresh Produce Exporters Association of Kenya (FPEAK)

13 The Canadian ‘Export Alert’ is available to other countries on a contractual basis. Information can be obtained from the Standards Council of Canada. See [www.scc.ca](http://www.scc.ca).

14 The Brazilian ‘Alerta Exportador’ is available to exporters without any associated costs, according to a pre-defined profile. The tool can be accessed through INMETRO’s website at [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas).

## Standards development

Developing countries should, to the extent that their resources allow them to, participate in the work of international standard-setting bodies and WTO committees to influence the impact of international decisions so that they are not detrimental to developing countries. Even though international standards are developed mostly by the major developed economies (e.g. Germany, France, the United Kingdom, the United States and Japan), and the rest of the world is largely a 'standard-taker', developing countries can still influence those standards that are of major importance to their own economies. This requires physical presence at the technical committee deliberations; corresponding members are never able to exert much influence.

*'Participation in ISO committee meetings helps developing countries to stay informed; it even allows them to obtain advance information about upcoming standards and technical regulations that could affect their exports.'*

Rajinder Raj Sud, Senior General Manager,  
Standards Management Department, SIRIM Berhad, Malaysia

International standards take three to five years to be developed. During this time the international technical committee meets at least once per year. In between meetings much time needs to be spent on the development of the committee draft documents, which requires input from industry and the national standards body. IT resources, a dedicated person in the national standards body and a mirror national committee are necessary to make a meaningful contribution. From a strategic perspective it may be necessary for the authorities to fund these sorts of activities in carefully selected cases, i.e. current or future major export products of the country. Public-private partnerships can also be pursued with the industrial associations of such sectors. ISO provides selective support through the Developing Country Programme, while FAO and WHO provide such support through their Trust Fund for Participation in Codex.

ISO and IEC each produce 500 to 1,000 new international standards per year. The Codex Alimentarius Commission also produces many standards every year that may be of great importance for many developing countries as their exports are often agriculture based. ISO and IEC between them operate about 400 international technical committees that meet at least once a year, over and above the tremendous amount of work done through electronic correspondence. It is therefore impossible for developing countries to participate in all of these activities. The funds are not available and neither is the technical expertise. Developing countries have to evaluate and prioritize their involvement extremely carefully to ensure that maximum gain is achieved. Involvement in the one or two technical committees that are important for the economy are much more important than trying to spread the involvement over many committees where little impact will be achieved.

An indirect benefit of participation is the opportunity to obtain advance intelligence, for instance on future ISO/IEC 17024 or the Codex Standard on Sardines. These are standards under development or revision that could have an important impact on a major economic sector of some developing countries.

### ***Participation in international standardization is essential***

#### ***ISO and IEC – an example from Malaysia***

**The issue.** Because of the requirement in the WTO TBT and SPS Agreements for international standards to be the preferred first choice as a basis for the development of technical regulations, participation in international standardization is no longer an option but essential for long term-success in the market.

**The strategy.** Malaysia became a member of ISO in 1969 and a member of IEC in 2000. Thereafter Malaysia took the strategic decision to actively participate in the standards development work. Examples of the initiatives taken by Malaysia to increase participation include:

- ❑ Hosting international standards meetings;
- ❑ Combining national and mirror committees;
- ❑ Supply of information on international standards to national committees and other stakeholders;
- ❑ Financial support for stakeholders' attendance at international meetings;
- ❑ Survey to identify current needs of industry;
- ❑ Regular promotional events; and
- ❑ Monitoring of new developments on international standards.

	2004	2003	2002	2001	2000	1999
<b>ISO TCs</b>						
Participating member	74	70	66	58	52	49
Observer member	122	119	120	120	68	43
Secretariats	4	3	2	2	2	2
<b>IEC TCs</b>						
Participating member	4	4	4	3	0	0
Observer member	78	78	79	78	78	78
Meetings hosted	5	2	1	2	2	1
Chair and/or convenor	6	6	6	4	3	3

This advance information of the contents of the standards might be of great importance to the local industry in preparing for the implementation of such standards. If the information reaches industry in time, it could also influence the contents of these standards before it is too late.

A method that has not been used to any great extent yet, but which could theoretically benefit developing countries, would be to develop a regional approach that could be presented or defended by one of its members during the international technical committee meetings.<sup>15</sup> In this case the developing countries in a specific region with common interests in the subject matter would agree on a common approach and then provide one member to attend the technical committee meetings with the mandate to argue on their behalf. This does presuppose a great deal of trust among the regional members, and proper communication before and after the technical committee meetings. The cost savings are obvious.

15 A similar approach is followed by developing economies in the WTO TBT Technical Committee, where the South American or Southern African region delegates might agree on a common approach to a specific TBT issue before the meeting and then support each other during the meeting, or present a point of view representing the region.

## Dissemination of information

Identifying and tracking the information is not enough. This information needs to be suitably disseminated to the relevant authorities and industries. It has to be provided proactively to the industry, which is generally not in a position to track it. The dissemination of information can be performed by the TBT and SPS enquiry points as well as the national councils of exporting associations, chambers of commerce and industry. A public–private partnership is very effective in getting the information to the right people. Again, the Internet is a very useful tool, especially in developing countries that often do not have strong postal services. In this regard, farming cooperatives could play a useful role in getting the information to their many members without access to the Internet.

*It is important to be proactive rather than reactive when it comes to collecting and disseminating information. Exporters always have to keep track of information.'*

Shyam Kumar Gujadhur, Senior Adviser on Standards and Quality Management, ITC

### *Challenge*

*Information is of vital importance. Industry and especially SMEs are not able to identify and review the vast amounts of information available. This would be a very useful service that the quality infrastructure can provide. Such a service can be established by:*

- ❑ *Focusing on capacity building of the National TBT and SPS enquiry points to gather, review and distil information from the WTO and international standards bodies for the business community and authorities;*
- ❑ *Developing or obtaining an efficient and effective information distribution software system that would reach relevant authorities and targeted business communities regarding information emanating from the WTO system and international standards bodies in the shortest time possible;*
- ❑ *Developing mechanisms to collate comments on WTO notifications from the authorities and the business community for transmission to the countries making the notification if the products are of interest for the country's exports;*
- ❑ *Establishing a public–private partnership between the enquiry points and organized business and industry bodies for disseminating and gathering information to and from the relevant industry and business sectors; and*
- ❑ *Strengthening trade and industry associations to gather and review relevant information from other than the official sources.*

*Language is also a problem, especially in developing countries. Most of the information comes in English, which not everyone can understand.'*

Bui Trung Nghia, Business Development Officer/  
Deputy Manager, Membership and Training Department,  
Viet Nam Chamber of Commerce and Industry

## Confirming and enabling compliance

Once the standard or the technical regulation has been established, then the major issue becomes the provision of evidence that the product or the service actually meets the stated requirements. This evidence must be presented in a manner that is plausible and that can be believed, otherwise the product or service might have to be retested or recertified, leading to additional time delays and cost. The question now arises how one provides the necessary assurances that the evidence of conformity can be trusted. In many cases this would only be possible through appropriate accreditation.

*‘When we talk about the cost of compliance, most of the cost is actually not compliance itself, but related to the demonstration of compliance.’*

Juan María González Vásquez, SEYMA, Costa Rica

*‘It can only take one bad shipment to “destroy” an entire country’s reputation.’*

Shyam Kumar Gujadhur, Senior Adviser on Standards and Quality Management, ITC

## Accreditation organizations

One of the major challenges facing industry is the acceptance of local conformity assessment results in the export markets. In recent years the slogan ‘Tested once, certified once, and accepted everywhere!’ has become the cry of industry, but has not yet achieved official status, nor does it command the respect of the major purchasing organizations. The level of trust that would facilitate such a state of affairs is still a mere dream. But quite a few initiatives have been mounted in recent years and some progress is visible.

At the international level, organizations such as IAF and ILAC have done much to have national accreditation bodies peer-reviewed and become members of their multilateral recognition arrangements (MLAs). Theoretically, national accreditation organizations may obtain such recognition within a four-year period. International experience, however, suggests that a time period of eight to ten years is more likely. This has to be taken into consideration by governments seeking to establish national accreditation bodies when assessing their resources and engaging in long-term budgetary planning.

*‘There is a common misconception about having a national accreditation body. Once it is set up, it is good, but having such a body does not mean that your products will be accepted everywhere in the world. Obtaining international recognition may take up to 10 years.’*

Martin Kellermann, International Consultant, Standards, Technical Regulations and Conformity Assessment, South Africa

There exist various cases where the market has recognized the competency of national accreditation bodies, and thus accepted the output from laboratories and certification bodies accredited by them. At the intergovernmental level, accreditation of conformity assessment bodies at national level together with MLAs between accreditation organizations is facilitating demonstration of compliance through mutual recognition agreements (MRAs) between governments.

There is currently a window of opportunity for developing countries to have their product certification schemes acknowledged by joining the recently established IAF MLA for product certification. Soon IAF will start the process of peer reviews of these schemes, which should eventually facilitate international recognition of the national product certification schemes.

## Regulatory authorities

### *Technical regulations*

General acceptance of accreditation as a measure of the technical competency of inspection bodies, test laboratories and certification organizations is not yet established among the regulatory authorities. In addition, regulatory authorities still require a 'legal hold' over conformity assessment service providers before they will readily accept their output. A good example can be found in the EU, where Notified Bodies (conformity assessment service providers acceptable to the EC) need to be resident in the EU, as well as providing evidence of their technical competency. Hence conformity assessment results from one country are not necessarily automatically accepted by regulatory authorities elsewhere, even if the national accreditation body is accepted internationally.

Another issue that needs to be borne in mind in this context is that the signatories to MLAs are different from the regulatory authorities. Recognition is all about building trust and confidence, and this does not happen through

### *Recognition through accreditation*

#### *The reality is still a long way off from the theory*

*In a recent survey conducted by ILAC, the following interesting results regarding the acceptance of accredited conformity assessment service providers by regulatory authorities in a number of economies were obtained.*

<b>Economies</b>	<b>Regulator accepts accreditation</b>	<b>Regulator accepts partner MLA accreditation</b>
11 Economies	Yes	Yes / usually yes
11 Economies	Yes = 3 Some = 7 Few = 1	Not normally = 6 Sometimes = 4
5 Economies	Yes = 1 Some = 2 Rarely = 2	Never / almost never



signatures on a piece of paper. From the perspective of the regulatory authorities this is a real issue as the accreditation body, which is not accountable for safety and health issues, is the signatory. In addition, the maintenance of the signatory status as a long-term issue is often not adequately addressed. This means that the equivalence in technical capability, which is the basis for the MLA, may not be maintained in the long term, thereby placing a question mark on the continued capability of the accredited organizations. This is of course even more unacceptable to the regulatory authorities. We still have a long way to go.

### *Sanitary and phytosanitary (SPS) domain*

In the case of traceability requirements for food products (in fact with regard to most of the SPS areas), the involvement of national regulatory authorities as the final arbiter of the integrity of exported products is absolutely necessary. This is because SPS and Codex Alimentarius requirements predate much of the more recent thinking regarding national quality infrastructures.

*'In the area of traceability, we need to be proactive. We have to go back and see what is happening in the main markets (United States, EU) and, if necessary, ask for assistance before it is too late.'*

Umran Kaggwa, Agribusiness Management Associates Ltd, Uganda

A concerted public–private sector partnership can go a long way in establishing and providing the required infrastructure. In South Africa, for example, the wine growers' associations worked with the Department of Agriculture (DoA) to set up a system and obtain funds to maintain exports to the EU over a two-year period. The DoA as the Competent Authority has to certify the wine for export (as required by the EU Directives) but it does so on the basis of conformity assessment results from both public and private laboratories and certification bodies suitably accredited – it does not test itself.

## **Foreign certification services**

In some instances, foreign certification services are needed for market access. In this case there is not much the authorities or the industry can do other than lobby the target market authorities to accept certification from local service providers that are appropriately accredited. Often this situation arises out of the exclusive agreements that developing country governments have entered into with multinational inspection and certification bodies.

In some cases the national certification organization can enter into a subcontracting arrangement with the foreign certification organization. One typical example is SIRIM conducting tests on behalf of the Canadian Standards Association (CSA) on Malaysian products destined for the Canadian market where CSA certification is a requirement. Another example is SABS in South Africa conducting surveillance testing and inspections on behalf of Underwriters Laboratories in the United States (UL) for South African products destined for the United States market where UL certification is needed.

### **Challenge**

*It is vitally important that the testing and certification of national service providers is accepted in the target markets by both the marketplace and the regulatory authorities. The challenge therefore is for authorities to pursue the appropriate mix of:*

- ❑ *Establishing a national accreditation organization and facilitating its peer recognition through IAF, ILAC and others;*
- ❑ *Negotiating recognition agreements based on proper accreditation and similarity of outcomes of technical regulations;*
- ❑ *Setting up private–public partnerships between regulatory authorities and conformity assessment service providers; and*
- ❑ *Facilitating subcontracting arrangements between the national organizations of the quality infrastructure and organizations in the target markets recognized by the authorities.*

## **Enabling compliance for the SME sector**

In many developing countries, the SME sector is the major part of industry. Larger industries can help themselves, once the required quality infrastructure is available. It is the SME sector that is particularly challenged. It requires support, first of all, to meet the quality requirements of the technical regulations and the marketplace, and then to demonstrate this compliance. As the SME sector is not financially strong, the cost of compliance should be kept as low as possible; otherwise SMEs will never connect to the mainstream economy. SME development programmes are in place in many countries, usually through the Ministry of Trade and Industry or similar, or through development banks at the national level.

The knowledge to provide assistance to SMEs is often available within the quality infrastructure, especially NSBs. Innovative solutions should be pursued by NSBs to assist SMEs in enabling compliance, without falling foul of international requirements regarding conflicts of interest especially where the NSB is the testing authority or certification body. To ensure that the services rendered are fully appreciated, it is also very important that SMEs pay, even if it is only a small percentage of the actual costs. In addition, the NSB also has to balance its books, and funds for SME development should not come out of its budgets.

*‘A national programme should be put in place by the standards institution to virtually take the SMEs by hand and take them through the entire process of compliance: inspection, testing, and certification. To ensure ownership and sustainability of the programme, cost sharing between SMEs and the government will be essential.’*

Group work of participants from Africa

Many programmes to develop the capacity of the quality infrastructure are available through the EU, USAID, UNIDO, ITC, Japan, and others. All these programmes do, however, require a proper structure in place as well as the

planning and commitment of the authorities, statutory bodies and organized industry. They have the greatest chance of being funded if they are focused on a specific problem area of importance also to the trading partner. A haphazard or general approach will not be funded.

### **Supporting SME development**

#### ***SABS did it with the blessing of the accreditation bodies – South Africa's example***

*In South Africa, SABS provides testing and certification services over and above its role as the national standards body (i.e. development and publication of national standards). Its role is further complicated by the fact that it acts as the regulatory authority on behalf of the Department of Trade and Industry. Yet SABS was able to establish an SME department within its structure whose sole remit was to support the SME sector in meeting and demonstrating compliance for products and systems standards, without compromising its accreditation of laboratories and certification services. This was achieved in open discussion with the accreditation bodies (RvA and SANAS) and the governance of the department was structured in such a way that SABS could demonstrate that it could not influence testing and certification decisions. SMEs had to pay SABS the full amount for the testing and certification services rendered, but were able to claim 50% of these costs from government institutions established to support SME development. Consultancy by the SABS SME department was paid in full from government funds.*

### **Challenge**

*SMEs are a vital part of many developing countries as they may be responsible for the bulk of the employment. It is therefore of vital importance to develop SMEs to the point where they can meaningfully participate in the global economy. The challenge is to:*

- Put support programmes in place that target the SME sector specifically in order to develop them to the point where their products demonstrably meet technical regulations and market requirements in the export markets;*
- Engage the national standards body, which often has the technical know-how, in such a way that it does not jeopardize its own accreditation; and*
- Channel funds in such a way that the SMEs have to pay a specific amount, and that the national standards body is appropriately compensated for its development role.*

## **Self-declaration of conformity**

Much has been said in international and regional forums regarding the idea of 'self-declaration of conformity' as the most cost-effective way of demonstrating compliance in both the voluntary and the regulatory domain. According to this approach, the supplier tests and confirms that the product meets requirements, and then states this as fact in transactions. No independent testing and certification bodies are directly involved. This is a nice idea, but one that will take a very long time to find any favour. It is especially in the regulatory domain that this idea will not be acceptable to the majority of the authorities for a very long time.

*'Declaration of conformity is a good way to reduce the costs of compliance. In fact, this kind of demonstration could be an excellent way to compete in developed markets.'*

Juan María González Vásquez, SEYMA, Costa Rica

It is generally accepted that such a system will work well only if product liability legislation is in place and effective, and if the supplier can be held accountable by aggrieved parties or the authorities. While product liability legislation may be in place in developed countries, it will be very difficult to apply if the supplier is resident in a small country on the other side of the planet, and as long as the perception persists that SMEs in such faraway places are technically not competent. It may be a different story if the supplier is a well-known organization resident in the country where the problem arises. It is therefore advisable that developing countries do not place their hopes on such developments.

### **Challenge**

*The cost of compliance, encompassing the cost of meeting requirements as well as the cost of demonstrating compliance, can be up to 30% of total production costs. The challenge therefore is to provide support mechanisms that target major or specific industries where the investment will make a difference in the export performance of the country. Success must be guaranteed, as it will breed further successes. A three-pronged approach is vital.*

- ❑ **Quality infrastructure.** *The quality infrastructure should be established in such a way that other sectors will also benefit, i.e. a holistic perspective should be kept in mind. Instead of replicating what is already established, enhance it.*
- ❑ **Industry.** *The capacity development of industry is as important as the establishment of the quality infrastructure – before you can demonstrate compliance you first have to establish compliance.*
- ❑ **Authorities.** *The regulatory environment requires appropriate attention. Failure to meet compliance requirements in the markets abroad is more often than not initiated by an inadequate regulatory framework or practices in the exporting country.*

## Part 3

# Emerging issues in the quality realm

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Over and above the issues regarding the establishment and maintenance of a proper functioning quality infrastructure providing the fundamental services such as metrology, standards, accreditation, and even traditional testing and certification services, new issues are continually emerging that challenge even developed countries.

The proliferation of quality management system requirements that increasingly affects developing country exporters has already been mentioned. But it is not only suppliers of products that face such challenges. Services are increasingly the target of similar quality management requirements, and with the proliferation of electronically based information services and the ease with which they can be accessed by unauthorized individuals, demands for security requirements for such systems are also on the increase.

This section subjects these emerging issues to greater scrutiny and makes the case that for developing countries to maintain and enhance their competitiveness, a strategic response from policy-makers and business leaders will be essential.

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## Conformity assessment

Conformity assessment requirements are continually increasing in complexity and scope. The original dream of the ISO TC 176 (the ISO Technical Committee for the ISO 9000 family of standards) leadership was that the publication of the ISO 9000 series of standards would put a halt to the proliferation of quality management system standards from a wide variety of sectoral interest groups, major purchasers, pressure groups, consultancy groups, etc. This has proved to be wishful thinking. ISO TC 176 had some initial successes within the ISO committee structures, where it could stop further development of such sector standards. Soon, however, the sluice gates were opened as interest groups endeavoured to shake the control of ISO TC 176, seen as a body of quality experts, which they believed could not deal with sector specific issues. Today we have an absolute plethora of such standards, each purporting to be a unique and absolutely necessary 'interpretation' of the ISO 9001 documents, and with no signs of abatement in sight. Some of the typical issues and challenges that manifest themselves, in particular within national certification bodies in the developing countries, are considered below.

### **Proliferation of management systems**

It is already difficult and expensive to develop capability and to obtain international recognition through relevant accreditation regimes for ISO 9001

and ISO 14001 certification. Yet additional sector-specific certification schemes such as QS-9000 or ISO/TS 16949 (automotive), FSC (Forest Stewardship Council for wooden products), BRC (British Retail Council for food products, etc.) are more and more often required to gain access to foreign markets in the developed world. The national certification body then has to acquire additional capability, and has to be accredited by the specific accreditation body for the specific sector (e.g. European or United States based body for TS 16949<sup>16</sup>). The national accreditation body, even if a member of the IAF or ILAC multilateral arrangements, is no longer good enough. All of this pushes the overhead costs of the national certification body sky-high, if not often out of reach. At the same time, if the national certification body does not offer a full range of certification services to the local industry that wishes to export, it may lose clients to foreign, multinational certification bodies that do so.

### Certification body problems

Certification bodies need to be accredited if they wish to enjoy market acceptance. Quite a number of the certification bodies operate in many countries. In this case it is usually only the head office that is accredited. Subsidiaries and especially franchises in smaller economies are then supposed to be internally audited by the head office regularly. The accreditation body will audit these subsidiaries or franchises on a sampling basis. The interval between such visits of the accreditation body can be as far apart as seven years depending on the amount of business the subsidiary generates, whereas the head office will be audited every year. All of this is in keeping with agreed international practices.

*‘Certification is a very lucrative business, which is why many entities try to get into this area. It is, however, important to realize that their activities as a whole critically affect the credibility of the quality system in place.’*

Parama Iswara Subramaniam, Senior Manager, Quality Management Systems Certification, SIRIM QAS International Sdn Bhd, Malaysia

This situation does lead to the perception, and sometimes it is even true, that national certification bodies are subject to more stringent requirements than those applied to the subsidiaries and franchises of foreign certification bodies (which are not accredited by the national accreditation body). A subsidiary in a developing country, however, is often perceived by the local certification body (which is assessed annually) not to be subject to stringent assessments, and to be flouting the accreditation requirements (e.g. simultaneously providing consultancy and accreditation services), but as being able to obtain business on the strength of the accreditation of the internationally known parent certification body. The situation regarding franchises is even worse, because the head office has even less control over their practices. Most of the efforts of IAF and ILAC to deal with these perceptions and to stamp out these practices have not yet met with much success.

<sup>16</sup> ISO/TS 16949 is an ISO technical specification, which aligns existing American (QS-9000), German (VDA 6.1), French (EAQF) and Italian (AVQS) automotive quality system standards within the global automotive industry.

## Auditor training

It is costly to train specialized auditors for ISO 9001 and, especially, for ISO 14000 certification (because knowledge regarding the legal environment of the country and its impact on environmental systems within the enterprises is required) and there is the danger of losing them to private industry organizations that pay higher salaries.

## Consultants

In a developing country, and especially in the SME sector, consultants are desperately needed to guide enterprises through the vagaries of implementing management systems and obtaining certification for them. Hence, many consultants operate in these economies; some are good, some are not. There is therefore an understandable desire on the part of the authorities and/or industry to register consultants in the area of management systems in order to protect the local industry. Questions and associated challenges nevertheless arise as to the competency of consultants, and the measures that can be taken should a consultant not provide an adequate level of service to industry.

## Occupational health and safety

In most countries, occupational health and safety (OHS) is a regulated domain, usually within the ambit of the Department or Ministry of Labour. At the international level, ISO tried in the mid-1990s to develop an international standard for OHS management systems. This notion was defeated mainly by some major industrial countries, as they did not wish to be subjected to another certification regime, supported by the claim that OHS fell under ILO responsibilities and not ISO. ILO then published a Recommendation based on the principles of ISO 9000, but OHSAS 18001 (a standard developed by a consortium of standards bodies and certification organizations) is much better known, especially in the certification industry.

*‘The beauty of OHSAS 18001 really lies in its intention, namely to ensure occupational health and safety and to reduce mortality and accidents.’*

Norafiza Saim, Senior Manager, Occupational Health and Safety Systems Certification, SIRIM QAS International Sdn Bhd, Malaysia

Everyone agrees that the implementation of an OHS management system can reduce accidents in the workplace, leading to savings through reduced insurance premiums and compensation due to injuries, and may even improve productivity. Some major purchasing organizations (sensitive to pressure groups) in developed economies are already beginning to require such certification, especially from developing country companies, yet the authorities in developing countries are of the opinion that their own legislation in this regard needs to be adhered to and not OHSAS 18001. This puts enterprises in a difficult position as their export products may not be accepted everywhere, and creates difficulties for the national certification body, which is seen to be treading on the toes of a ministry.

## Review of ISO 9001

The ISO 9000 series of international standards, like all standards, is continuously reviewed and updated. The next cycle is scheduled to end with the publication of the second revision of ISO 9001 in 2008. Within the major economies various groupings are currently working on these revisions. Another enterprising proposal in this regard is exemplified by an initiative by Japan. The current ISO 9001 series of standards is based on eight quality management principles; Japan's proposal is to enlarge this to 12 quality management principles. Japan believes this will enhance the current version by broadening the total quality management (TQM) principles it contains. As the additional principles have mainly to do with the quest to continuously improve productivity and products in small steps, Japan believes such an approach would support the development of the SME sector in particular to improve competitiveness.

## Quality management in the services sector

The services sector is the largest and fastest growing part of the international economy, currently responsible for more than 60% of global output. In many countries, services provide more than 60% of all employment. In the ACP countries, the average share of services in GDP is 50% (varying from under 5% to as high as 75%). Trade in services is, however, experiencing major barriers to trade because of differences in regulatory requirements, as was the case for standards and technical regulations in the past.

During the Uruguay Round of talks, which led to the establishment of WTO, services featured quite prominently. Negotiations to establish a General Agreement on Trade in Services (GATS) were therefore initiated. After complex, protracted and very difficult negotiations in which many countries were involved, the talks were concluded in 1995.

*'I have been involved in the GATS Schedule for Belize. The problem here is that the private sector is not sufficiently involved, which is crucial to move forward.'*

Michael Deshield, Director for Food Safety,  
Belize Agricultural Health Authority

GATS is to a large extent still 'work in progress'. This has come about because GATS requires a tremendous amount of interpretation (which has not happened), and consequently it is not well understood at all. In addition, for GATS to be implemented fully, every WTO Member has to prepare and lodge a schedule of specific commitments.

Some of the strategic issues that are emerging and will soon require some far-reaching decisions from developing countries are described below.

- In the GATS, four modes of trade are defined. Of these, developed countries favour mode 3, 'commercial presence' (where the supplier establishes a commercial presence abroad), whereas developing countries favour mode 4,



the 'movement of natural persons' (where the provider of the service crosses the border). During trade negotiations these differences will come to the fore, and developing countries may find themselves at a disadvantage.

- ❑ Three service sectors – telecommunications, business services, and education and training – have been shown to have a marked result on the effectiveness and efficiency of services in all economies, and determine to a large extent the growth potential and patterns. Developing countries face a challenge in providing services in these three service sectors, where they are generally weak.
- ❑ Every country has to lodge a GATS Schedule with the WTO. This Schedule has to provide details regarding the access foreign service providers will be given in specified service sectors and subsectors including the conditions under which this access will be granted. GATS lists 12 sectors with a total of 155 subsectors that have to be addressed. The establishment of the GATS Schedule is not an easy task. The consequences are wide ranging. If it becomes a free-for-all immediately, local service providers may suffer unnecessarily. On the other hand, if restrictions are too onerous, the country will be locked out of the world trade in services and suffer as well. The need for a proper public-private partnership to develop an appropriate GATS Schedule is therefore very strong.

*'Talking about quality in the services sector, you should focus first on identifying and fulfilling the needs of different customers, not on developing and complying with technical or more quantitative requirements.'*

Mohd Razali Hussain, Director of National Productivity Center, Malaysia

- ❑ In many developing countries, tourism and travel are a major contributor to the national economy. Over and above the few large tourism companies, many SME sector enterprises provide services in this sector, including bed and breakfast establishments, taxis and tour guides. Many authorities, wishing to protect the name of their country as a viable tourist destination, seriously consider regulating this industry. Care should, however, be taken not to over-regulate services following isolated incidences of non-compliance, as this might unnecessarily stifle entrepreneurship.
- ❑ Consistency and quality of service are paramount for all suppliers, otherwise they might soon find that their customers have moved on. This means that the personnel and the machinery involved in providing the service need to function optimally at all times. Issues such as on-time delivery, courtesy in business dealings and the appropriateness of the service in the context of the cultural background of the customer are extremely important over and above the technical suitability of the service.
- ❑ There was an international standard that provided guidelines for the implementation of ISO 9001 in the services industry (ISO 9004-2) but unfortunately it has been withdrawn to be reviewed. Service companies are therefore certified to whatever the interpretation of the certification organization considers appropriate in terms of ISO 9001. The content of such interpretations is therefore important when deciding on the value of such certification.

- In many countries public (e.g. mandatory grading system for hotels) or private organizations (e.g. AA or Michelin Guides for tourist establishments) provide a measure of the quality of service delivery. Often this type of grading is based on the list of available services without making any judgement on the quality of such services. In addition, many such rating systems are based on a self-assessment. Management systems (including certification), however, should take into account the quality of the service, and not only the availability of services – is the bed comfortable, rather than is a bed available; or is the food palatable, not just is the kitchen available 24 hours per day. Grading systems that do not take the quality experience of the customer into consideration will soon lose all credibility if the customer continues to experience bad service even though the enterprise providing the service is graded or certified.

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## Quality and security

The current industrial and business environment is typified by the explosion of information technology (IT). The extensive use of computer systems in all walks of life, in business, by the authorities and even at home is unprecedented. The ease of access brought about by the Internet has, however, also created many security problems, especially regarding the integrity of computer systems and personal data. Organizations therefore have to establish systems that ensure integrity. Even a home computer is not immune to major security threats. Therefore, major purchasers in developed countries require business partners (especially in developing countries) to have IT security systems in place at the same level of sophistication as they do. If this is not the case or cannot be demonstrated, they will be reluctant to do business for fear that their own systems will be compromised, as much of business communication now relies on IT systems.

*'We live in a global village. Thus, if you want to trade globally, you have to deal with security-related issues.'*

Ariffuddin Aizuddin, Manager,  
Security Management & Implementation,  
National Information Security and Emergency Response Centre, Malaysia

Associated strategic considerations include the following:

- Security of information and IT systems add to the cost of doing business. It is, however, important to tackle them because trading partners will audit potential partners to check their security level before sharing information. Independent certification systems are also starting to be employed in this regard (e.g. ISO/IEC 17799, 'Code of Practice for Information Security Management').
- Developing countries face many constraints on building capacity related to 'security' issues. However, these issues must be addressed and resolved if a company is to do business where 'security' requirements are fundamental.

- ❑ Information security management systems require a proper risk assessment and risk management strategy, whereas this is not the case for ISO 9001. The former is organization based, whereas the latter is consumer based. You need a quality infrastructure to have a secure environment but not vice versa. This entails a different approach to the management system than what the enterprise may be used to in the normal 'quality' environment. Whereas quality systems are generally defined by satisfied customers, security systems are based on the specific requirements of the business, and these have to be determined quite carefully. Security systems therefore require much deeper involvement by the company.

*'Security requirements actually affect trading a lot. Small producers in African countries are, for example, not able to export to the United States. Why can they not provide assistance to put adequate security systems in place to enable us to meet these requirements?'*

Umran Kagawa, Agribusiness Management Associates Ltd, Uganda

### **Challenge**

*Developing countries have a hard time already in establishing the basics of a quality infrastructure. To make matters worse, the goal posts are continuously moving. Contrary to what developing countries might like, namely a stable environment, the real environment is everything but stable. Strategy-makers and policy-makers are therefore challenged to*

- ❑ *Take into consideration the ever-increasing complexity of the international requirements regarding certification;*
- ❑ *Ensure the establishment of proper information systems that can keep track of all the changes;*
- ❑ *Ensure the establishment of a sound methodology (i.e. an advisory body representative of both public and private industry) to review the information and extract that which is relevant to the local industry and authorities;*
- ❑ *Provide for development mechanisms in order for the continuous development of the quality infrastructure as well as suppliers to meet the new realities; and*
- ❑ *Ensure that management of the quality infrastructure organizations does not get complacent once a specific goal has been reached.*

## Part 4

# Building an export-oriented quality infrastructure – a practical approach

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Meeting technical and quality requirements in the international marketplace is a tall order. But as competitive pressures are mounting, it is a challenge that a national export strategy must address.

Understanding the elements of a national quality infrastructure, the organizational set-up and the specific infrastructure needs for meeting regulatory requirements is not easy. Setting up an enabling quality infrastructure is complex, time-consuming and expensive.

It requires overcoming a number of set-up and organizational challenges. It requires preparing and supporting existing, potential and aspiring exporters for the international market by providing them with relevant and complete information to meet both mandatory and voluntary requirements as well as consumer preferences in target markets. It requires establishing the right institutions and support programmes to confirm and enable compliance of existing, potential and aspiring exporters. And it requires the ability of a national quality infrastructure to live up to continually changing, increasingly complex and ever more stringent quality requirements.

The existence of such a quality infrastructure in the country is a fundamental aspect of ensuring the competitiveness of the export sector. Nevertheless, it is an aspect that has not been given sufficient attention by export strategy-makers in many developing countries and transition economies.

If reforms are being tackled, they often concentrate on a few isolated issues, not on a revision of the entire system. The lack of communication and coordination between the regulatory authorities responsible for the implementation and maintenance of technical regulations and the creation of an enabling quality infrastructure, as well as between the public and private sectors, is particularly disconcerting in this context.

The need to do something about the effectiveness and efficiency of their national quality infrastructures is thus felt with increasing urgency in the developing world. The questions that arise relate to what needs to be done and how they should embark on such a process of review and reform.

Given the complexity and the required investment involved, best practice suggests taking a step-by-step approach to building a national, export-oriented quality infrastructure. While the process should be tailored to the particular national or regional situation and take into account specific development and commercial priorities, the experiences of a number of countries that have got it right (such as South Africa and Malaysia; see 'Innovative strategies in selected country approaches' on pages 59–64) as well as the consultation discussions

point to several common steps or issues that could provide a useful reference point for countries planning to embark on a review of their national quality systems. It is important to note that in the examples of South Africa and Malaysia, a holistic review of the system was instrumental in arriving at a positive outcome, even though the solutions were not the same.

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## Review process considerations

Even though a review of individual organizations in the quality infrastructure can bring about gains, experience in many countries has shown that such a review has to take place at national level and has to involve the whole of the quality infrastructure in order to maximize the gains. A national review might find that the organizational infrastructure has to be totally re-engineered, something which will not happen if organizations are reviewed in isolation.

In most countries, a specific government department or ministry has been given the responsibility of dealing with the WTO TBT Agreement, e.g. the Department of Trade and Industry. This department or ministry should accept responsibility for the quality infrastructure if it has not done so already. In countries that have been successful in reviewing and re-engineering their quality infrastructures, this department has taken the lead in this process, because without official sanction and support, the quality infrastructure will not be able to get off the ground or function optimally. Another reason for a government department to take the lead is that the quality infrastructure needs to integrate with the technical regulation system. Regulatory agencies need the assurance of ‘officialdom’ before they will participate.

*‘The government has to work together with the private sector to encourage the enterprises to meet quality requirements and thus to increase their exports. The government clearly has to play its positive role.’*

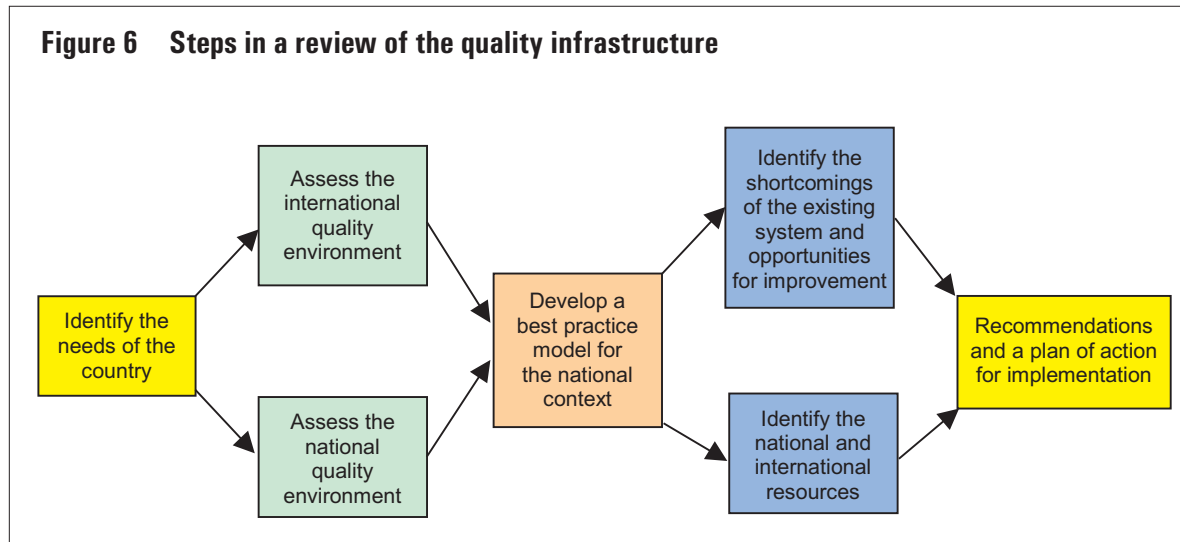
A. Aziz Mat, General Manager,  
SIRIM Berhad, Malaysia

A ‘best practice’ approach is depicted in figure 6. Important attributes that define a best practice approach include the following:

- ❑ The process has to be consultative – both the public and private sectors should be meaningfully involved as equal partners in the outcome of the process;
- ❑ The process has to be transparent – information regarding the evaluation and the decision-making process should not be hidden from the public eye; and
- ❑ The process should ensure that some early and significant gains are made in order to persuade the generally conservative quality people that it is a worthwhile exercise.

Such a review process should be embedded in national strategies, such as a national export strategy, an industrial development strategy or similar. In this way the appropriate strategic priorities and cross-sectoral elements that require attention would find their way into the implementation plans.

Another review process consideration would be that such an effort may, most usefully, be embedded in a national export strategy design effort, that determines the strategic priorities and identifies those cross-sectoral elements that require review or upgrading. Such a commitment would be another important process consideration.



## Determining the optimum national quality infrastructure

As shown in the previous parts of this document, developing countries face the all-encompassing need to develop, implement and maintain a quality infrastructure that will serve the needs of their industry and authorities, on the one hand to enhance their competitiveness in world markets, and on the other hand to ensure the safety and health of society at home. But achieving a fully fledged model quality infrastructure comes with a hefty price tag, one that many developing countries will be severely challenged to finance. Hence it is of even greater importance that developing countries make the correct choices and first implement that which is absolutely necessary and within their means, and then progress later to the ‘nice to have’ elements of a fully developed quality infrastructure.

The following could be used as a high level checklist to institute a review of the national quality system and to develop a best practice model including steps for its implementation. Obviously, a tremendous amount of detail is required to bring it to fruition, but that sort of detail would need to be informed also by national practices.

### Identify the needs of the country

The needs of industry in general, specific sectors, individual businesses and the business/trade support network regarding quality infrastructure-related services should be carefully determined through dialogue. This requires the responsible authorities, organized industry and business and support organizations to meet as equal partners in some sort of formal forum or series of meetings.

The needs of the various authorities (e.g. ministries and regulatory authorities) require a similar approach. The two domains can be handled separately or combined. For reasons of transparency and efficiency it would, nevertheless, be prudent to combine them.

*'A national forum with wide presentation of all the stakeholders is a precondition for a successful quality infrastructure to be put in place. Such a forum could allow for discussion and consensus-forming between public and private sectors.'*

Group work of participants from Latin America and the Caribbean

### **Assess the national quality environment**

In most economies, even in the least developed countries, there exist some organizations that are involved in elements of the quality system such as standards, inspection, testing, metrology and certification. Many of them will be government or semi-government organizations. These should be identified and their current range of activities quantified.

Many government departments are involved in the development, implementation and maintenance of technical regulations. They should likewise be identified and their potential needs as regards the quality infrastructure determined. This will not be an easy task and will require a lot of explanation because of the wide gap between regulatory authorities and the standardization environment.

### **Assess the international quality environment**

It is very useful to identify economies that are at a similar level of development as oneself and try to obtain information regarding their strategies for the development, implementation and maintenance of a quality infrastructure. Quite a few developing countries have successfully completed an in-depth review of their national quality infrastructure, even though they may still be in the process of implementation. A good point to start such a search would be the national standards bodies because they are invariably at the heart of such a review, and as the national WTO TBT enquiry point they would know about changes regarding the quality infrastructure.

A second avenue of knowledge is the efforts of various OECD countries to affect regulatory reform programmes. These often include a review of the role and functions that the quality infrastructure plays in the regulatory area. Care should be taken that the programmes of developed countries are not slavishly copied; developing countries should instead learn from their fundamental thinking and apply it to their own situation keeping in mind the prevailing realities. The developments in trading regions such as SADC, EAC, South America, Europe, West Africa, ASEAN and APEC countries also contain key lessons.

### **Develop a best practice model for the national context**

Once all the information is available an organizational construct of the optimum quality infrastructure should be developed through a proper

consultative process between all the players, including organized industry and business. International consultants can provide meaningful input. The international quality system, funding realities, local custom and practice, international accreditation requirements, the legislative environment and trading partner preferences will all play a role in reaching a workable solution.

As to the process of arriving at an appropriate quality infrastructure, it is very important that the preservation of the current system should not overshadow these deliberations. It would be far better to use a ‘greenfield’ approach, i.e. develop a best practice as if no quality infrastructure exists at all.

Substantive decisions will have to be reached regarding the following questions:

- Will one or more organizations be required?
- Which of the standards, metrology, testing, certification and accreditation activities can be provided by one organization? (This saves on overheads, but spreads the focus of management.)
- Which of these will be funded through government grants and which by clients (private and public sector) paying for services rendered? Avoiding conflicts of interest is an important challenge as is ensuring good governance.
- How can the effective business management of such an organization or organizations be provided for while at the same time ensuring that all stakeholders have an influence on the policies and offerings of the quality infrastructure entities?
- Should partnership arrangements with regional infrastructure bodies be entered into?

The answers to these questions will depend on each country’s context and specific priorities, commercial as well as political, and available resources. While standard answers are not available, as indicated in part two, a focus on the key challenges to overcome and other countries’ experiences go a long way to providing answers that are appropriate to each country.

*‘Every country is different and starts from a different level of quality infrastructure. Strategies thus have to be developed in line with the specific needs of each country. For example, while Malaysia has a very advanced infrastructure in place, in the Lao People’s Democratic Republic and Cambodia no proper conformity assessment bodies have been established yet.’*

Group Work of Participants from Asia

## **Identify the shortcomings of the existing system and opportunities for improvement**

Once the best practice quality infrastructure has been arrived at, the gap between it and the current set-up has to be clearly identified, and opportunities for improvements carefully enumerated. This gap analysis would lead to recommendations and a roadmap for implementation. At this stage, the following issues (but not limited to this list) need to be identified:



- ❑ Changes to legislation (this could take a number of years to establish);
- ❑ New organizational structures or corporate identities, or changes to existing ones;
- ❑ Development of personnel;
- ❑ Establishment or upgrading of laboratories; and
- ❑ Increased involvement in international and/or regional quality-related organizations.

### Identify resources

In every country resources do exist, even though they may be inadequate for the job at hand. It is important that these be identified, including financial resources (from both the public and private sector), human resources and the institutional resources that are already in place.

*‘For a quality infrastructure to work effectively, technical competence and adequate resources and facilities are essential.’*

Khalida Mustafa, Principal Consultant, SIRIM Berhad, Malaysia

A second avenue would be to approach the various aid agencies that are currently active in this specific field. These include agencies of the European Union, the United States, the United Kingdom, Germany, the Nordic countries, Japan, UNIDO and ITC. Very often the main trading partners of developing countries would be the first port of call, as it is in their interests as well that the developing country has an efficient and effective quality infrastructure to support and enhance trade.

*‘Developing nations need the support of the international community and developed nations to build up the necessary capacity and capability in the quality realm.’*

Khalida Mustafa, Principal Consultant, SIRIM Berhad, Malaysia

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## Implementing the plan of action – the great re-engineering

### Prioritization

The activities listed above need commitment first and foremost from the authorities. Secondly, resources (funds and expertise) are required to establish the laboratories and other organizations of the quality infrastructure. These resources are often in short supply in developing countries. It is therefore very important to prioritize carefully what needs to be done. Although the standards, metrology and accreditation infrastructure has to be provided by

government, industry still needs to be consulted to identify the ‘needs’ rather than the ‘nice to have’ elements. On the other hand, industry can and should be involved in the provision of testing and certification services.

Clear rules as to how this should be done are nevertheless difficult to provide here, because economic systems, legal systems, custom and practice and available infrastructure vary a lot from country to country. Information that could help to establish priorities includes trade data, in particular export data, and existing health and safety concerns within the country (e.g. compulsory standards or technical regulations for products that may constitute health and safety hazards should they fail). Also important are policy and future strategic priorities regarding trade, safety, health and the environment (e.g. are new environmental standards to be implemented; is a specific sector being targeted for special development support in order to foster exports).

In the context of the development of a national export strategy, the determination of priority sectors will likely be a useful indicator of the precise quality infrastructure needs and the sector-specific support a country requires with a view to maintaining and enhancing competitiveness. To formulate a plan of action, intense dialogue and consultation between the authorities and the private industry is as vital here as during the initial identification of the needs.

The focus should, however, not exclusively be placed on the priority sectors. A quality infrastructure that is as effective and relevant as possible will provide support to enterprises and exporters across the board. This begins with the timely provision of information about new quality requirements, which can open up new export opportunities within an instant, both in and outside of priority sectors.

Help may also be available from organizations such as UNIDO and ITC, from donor organizations such as USAID, DfID, GTZ, Sida, and from others, including, international consultants. It is also in the interest of the major markets such as the EU, United States, Canada, Japan and others to have proper functioning technical regulation systems and quality infrastructures established in developing countries with which they trade. Hence they are quite willing to provide assistance in the framework of current trade agreements. The major requirement is that the developing country has a clear concept of where it wants to go. A strategic approach based on a realistic assessment of the current quality situation and existing resources together with clearly formulated objectives will not only assure domestic buy-in, but is also likely to facilitate international support.

## **Sectoral initiatives**

As already indicated, a specific sector or industry may require special and dedicated efforts within the quality infrastructure to secure and maintain markets, both local and export. As part of a national export strategy effort, these would have already been selected.

Typical examples for developing countries include food exports or the local tourism and travel industry. In these cases, specific programmes to establish dedicated laboratories, inspection and/or certification regimes may have to be pursued. This may well entail training of the quality infrastructure staff as well as those in industry, and provision of equipment, laboratory buildings, air conditioning, and much more. Such programmes should, however, be established within the overall quality infrastructure design to avoid costly and

unnecessary duplication. Once such duplication has been established it will be very difficult to get rid of it. Capacity building within the agreed structure is therefore of paramount importance.

## Implementation of the changes

Once the optimum quality infrastructure has been arrived at through consultations, the current structures may well require massive changes. This will not come about without outside intervention, and it will be very painful. The choice has to be made whether a gradual changeover to the new structures will be more appropriate, or whether an immediate massive change has a better chance of success. In most cases a massive change will be more traumatic for the people and will require a ‘change agent’, whereas a more gradual change may prolong the agony, and may also foster silent sabotage from within the current system.

It is to take all the stakeholders along, especially the private sector; otherwise their trust in the system might be seriously compromised. ‘Change agents’ that leave after the changeover may be appointed, providing space for the more permanent staff to settle the organizations once the changes have been effected. Standards people are by nature conservative and will resist change quite effectively, so often need to be ‘shoved’ along quite forcibly. (This was nicely illustrated in the case of South Africa and Costa Rica, where the standards bodies were not particularly happy with the changes that had to be brought about, and external ‘change agents’ had to initiate them.)

Once the changes have been effected, appropriate steps need to be taken quickly to obtain national, regional or international recognition through accreditation, legislation or whichever way needed.

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## The regulatory domain

### Technical regulations

Just as technical regulations have been around for decades, the same can often be said about the government departments that are supposed to develop and implement such compulsory standards. Most countries have a number of them, each working in splendid isolation. The country does not have a common policy for the development, implementation and maintenance of technical regulations. This is detrimental to trade and may well compromise the safety and health of society. Moreover, ongoing trade negotiations consider technical regulations in great detail, and if the country cannot present a holistic picture, successful negotiation will be difficult to achieve.

Therefore, once the decision has been made to re-engineer the quality infrastructure, it is of great importance that the technical regulation environment be subjected to a similar fundamental re-engineering process, often known as a regulatory reform process. The main government departments or ministries responsible for technical regulations should form an interdepartmental liaison committee, whose objective would be to:

- ❑ Determine current custom and practices, and the legal environment;

- ❑ Develop a common policy for the development and implementation of technical regulations recognizing emerging international best practices;
- ❑ Establish appropriate links to the quality infrastructure, especially the use of standards as the basis for technical regulations, and the appropriate recognition of the role of metrology and accreditation in determining the technical capabilities of conformity assessment service providers;
- ❑ Establish a programme to review all technical regulations on the statute books, and set up a system to ensure that future technical regulations meet policy requirements and objectives.

It is useful if the members of such a committee do not initially include the regulatory agencies responsible for the administration. A fundamental policy rethink is needed, not a tinkering with the administrative system. Issues that need to figure in the debate are foreign trade policies, safety and health policies at home, environmental policies, labour practices, how open should the economy be, and many more. Regulatory agencies often wish to preserve, even enlarge their domain, hence they may hamper a sound rethink.

## SPS measures

During recent years there has been a considerable international effort to strengthen the infrastructure required for modern and integrated or holistic control along the whole food chain ('farm to table approach'). This means that the whole food chain – producers, traders, importers and retailers – should accept the main responsibility for checking that SPS regulations are complied with, leaving the food control authorities mainly with auditing and training functions. This would be supported by mandatory inspection by national authorities to ensure that all activities during production, handling, storage, processing and distribution are safe and conform to the sanitary and phytosanitary requirements for exported and imported products.

*'The lack of a harmonized quality assurance or food safety law makes production in Malaysia more expensive and tricky because we have to install or establish different sets of procedures to comply with the food safety or quality requirements of different countries.'*

K. Palasuberniam, Assistant Director, Export and Certification Section,  
Crop Protection and Plant Quarantine Division,  
Department of Agriculture, Malaysia

Worldwide trade in food and food-related products depends on the use of safety assurance, and sanitary and phytosanitary inspection and certification systems. These systems should reflect the relevant principles contained in, for example, the Food Import and Export Inspection and Certification System (Codex Alimentarius), the Export Certification System (IPPC) and the Animal Health Code (OIE).

If the developing country's SPS system has not been updated and streamlined in recent times, then a programme similar as for technical regulations will be indicated.

## ***The technical regulation domain is in dire need of reform – South Africa's experience***

### ***Current situation***

*A number of government departments are responsible for the development and implementation of technical regulations in South Africa, either by themselves or through dedicated regulatory authorities. All of these government departments pursue the development and implementation of technical regulations quite independently from each other, each within their own area of responsibility. As a result:*

- The regulatory system of South Africa is fragmented;*
- The transparency of the system leaves much to be desired;*
- Impact assessments are currently only conducted in about a fifth of the cases; and*
- The technical requirements are a mixture of performance-based standards and prescriptive product standards.*

*In consequence:*

- Implementation varies from very good to virtually ineffective;*
- The safety and health of society is compromised; and*
- The consumer often pays the penalty for the less than optimum technical regulation regime.*

*This has serious implications for South Africa in its international and regional trade relations:*

- Its compliance with the WTO TBT Agreement could be challenged; and*
- Concluding new trade agreements is proving to be difficult.*

### ***The review process and future developments***

*The Department of Trade and Industry (DTI) obtained Cabinet endorsement in October 2002 to establish an Interdepartmental Liaison Committee to initiate a Technical Regulation Reform Process. This process has as its stated goal the development of a uniform approach to the preparation, adoption and monitoring and review of technical regulations – a South African Technical Regulation Regulatory Framework.*

*The Liaison Committee, made up of senior officials responsible for policy and strategy, initiated a review of the current practices followed by the various government departments and their regulatory agencies. On the basis of this knowledge DTI developed a policy paper (finally published in March 2005) in which the principles of the uniform technical regulation approach were enumerated, including:*

- Transparency.*** *Stakeholders have the right to be informed and involved in the development of technical regulations.*
- Proportionality.*** *Government intervenes only when it is absolutely necessary.*
- Necessity.*** *Government has to be able to justify its interventions.*
- Targeted.*** *Technical regulations should focus on the core problem and minimize unintended effects.*
- Non-discriminatory.*** *No difference in dealing with domestic and foreign products.*
- Harmonized measures.*** *Use the essential parts of international standards in performance-based technical regulations.*





*Five building blocks will make up the South African Technical Regulatory Framework, these being the legislator, the regulator, technical requirements, conformity assessment requirements and sanctions for non-conformance. For each of these building blocks, general and specific processes and requirements will be developed once the policy has been accepted and promulgated. Impact assessments before any new technical regulation can be promulgated will be compulsory.*

*These principles will be enforced through a new Technical Regulation Reform Act which will also see the establishment of a Technical Regulatory Reform Office, give the Interdepartmental Technical Regulatory Committee legal standing, and establish a Technical Regulatory Advisory Forum where society and industry can have their say.*

*The Technical Regulation Reform Office will:*

- Monitor the technical regulation activities of all the relevant government departments and their regulatory authorities;*
- Ensure that the principles of the regulatory framework are meticulously followed;*
- Involve the quality system support infrastructure in the appropriate manner; and*
- Have technical regulations already on the statute books reviewed for compliance with the regulatory framework.*

## Generate action, but focus and align this action across all the players

Carefully thought through initiatives should be chosen to re-engineer the quality infrastructure. It is easy to make mistakes; it is not so easy to fix them. These should be designed to generate progress and momentum. The initial steps don't need to be overly ambitious, since their primary role is to achieve 'early wins' and build trust among the stakeholders. Such 'early wins' should include things that can be experienced by the personnel or the clients, including:

- A clear identification and separation of the various responsibilities for standards development, accreditation, metrology and testing;
- A clear separation of activities that are funded by government from those that should be based on the 'user pays' principle.

After these first successful initiatives, more ambitious actions can be planned. This is where a formal structure and programme will be useful to focus and align the activities across the growing number of players involved. The consultative process should be utilized to its fullest extent, even at this stage.

## Extend and sustain

Building a national export-oriented quality infrastructure success that is conducive to building a strong and sustainable global competitive position is a challenge that never ends. To maintain momentum, all members of the quality infrastructure must recognize its ongoing relevance to the country's ability to compete internationally, and the importance of being a part of it. This

momentum has to be maintained even as available resources, financial and human, are often in short supply. With these objectives in mind, a successful quality infrastructure requires:

- ❑ A constant focus on upgrading the capabilities of the entities within the quality infrastructure;
- ❑ Coordinating an ever-growing number of complex quality infrastructure projects;
- ❑ Building more and stronger linkages and interactions within the global value chain;
- ❑ Continually focusing on upgrading the basis of competition; and
- ❑ Flexible approaches to grow in line with strategic priorities.

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## Innovative strategies in selected country approaches

Because of the pressures facing their quality infrastructures, quite a number of countries have in recent times embarked on major reviews of their systems. These have resulted in some major and painful overhauls of sometimes well-established but no longer effective or efficient systems. The specific experiences of South Africa, Malaysia, Costa Rica and Benin show how varied and complex the whole issue of a quality infrastructure is and can be. At the same time, their experiences contain some important lessons that may help other countries busy with or planning similar reviews and trying to devise their quality infrastructure in a more strategic manner.

### South Africa

Following the change in the political environment after 1992, the role of the various institutions in the government and semi-government sector within the quality infrastructure were reviewed. As a result of these reviews, which took a holistic view of the quality infrastructure as serving both industry and the authorities, a major re-organization of SABS was initiated, as well as of the other institutions, such as the National Metrology Laboratory (NML) and the South African National Accreditation System (SANAS). At the same time, the technical regulation framework was extensively overhauled, as it was no longer effective or efficient and its lack of cohesion was beginning to have a negative effect on trade negotiations with major trading partners.

The major changes affecting the organizational structure of the SABS are as follows:

- ❑ SABS was an integrated institution providing standards, testing and certification on a technology basis, including the administration of technical regulations on behalf of DTI.
- ❑ SABS was separated into two operating entities, Standards South Africa (StanSA) and SABS Holdings (Pty) Ltd. The former is deemed to be the non-commercial arm, and the latter encompasses all the commercial activities such as testing and certification. StanSA receives government funding, whereas SABS Holdings receives none.
- ❑ The regulatory activities, including legal metrology, of SABS will soon be transferred to an independent regulatory authority.

At the operational level many changes were effected, some of them quite innovative in their approach.

- ❑ In order to persuade all of the regulatory authorities to use standards as the basis for technical regulations, StanSA is pursuing MoUs with them which would give the regulatory authority the chair of the technical committee and a final veto right on standards destined to be used in technical regulations.
- ❑ SABS Holdings, with all its laboratories and certification services accredited, is in a good position to be the conformity assessment service provider of choice to the authorities and regulatory agencies.

Some of the main lessons learned during the re-engineering of SABS were:

- ❑ It is very important to engage the industry and other stakeholders from the very beginning, otherwise trust in the integrity of the organization may be seriously compromised.
- ❑ By totally separating the standards development from the laboratories and the certification activities, the focus of standards development shifted from meeting the needs of the organization to meeting those of the country.
- ❑ It is very difficult to change the habits of a lifetime, especially of standards people who are by nature very conservative. External support during the re-engineering is essential.
- ❑ It is easy to make mistakes; it is not so easy to rectify them once they have been made. Therefore every change needs to be carefully evaluated before it is implemented. If it isn't broken, don't fix it.

As regards the technical regulation domain, South Africa has embarked on a total overhaul of its systems. The various government departments will remain responsible for the development and implementation of technical regulations, but will have to follow prescribed patterns aligned with emerging international best practices. Legislation to establish a regulatory reform office is in the process of being developed. Technical regulations will be based on performance standards; regulatory authorities will not have laboratories; and the national quality infrastructure will be fully integrated into the technical regulation activities. Before developing any new technical regulations, the regulatory authorities will have to conduct an impact assessment to ensure that technical regulations are implemented only when they are really necessary.

## Malaysia

The Standards Institute of Malaysia (SIM) and the National Institute of Scientific and Industrial Research (NISIR) were merged in 1975 to form the Standards and Industrial Research Institute of Malaysia (SIRIM). In 1996 the Standards of Malaysia Act was promulgated and the organization was incorporated as SIRIM Berhad. A subsidiary, SIRIM QAS Berhad, was formed to provide certification services on a commercial basis, and to deal with conflicts of interest. The Department of Standards Malaysia (DSM) was established at the same time to publish the national standards and to act as the national accreditation body for Malaysia (taking over from the Malaysia Accreditation Council). SIRIM was contracted to develop national standards and to provide conformity assessment services to regulatory authorities with regard to technical regulations. In this way the government kept control over



the policy directions of standards but did not get involved in the development of them. The potential conflict of interest between the accreditation organization and SIRIM was also elegantly solved.

*‘To avoid conflicts of interest, certification and accreditation have to be separated. This is why in Malaysia, these activities were taken away from SIRIM in 1996.’*

Mariani Mohammad, Director General, Department of Standards, Malaysia

In order to increase the participation of industry in international standardization activities, which is seen as of vital importance for Malaysian industry, Malaysia engaged in:

- ❑ Hosting international standards meetings;
- ❑ Combining national and mirror committees;
- ❑ Supplying information (including the monitoring of new developments) on international standards to national committees and other stakeholders;
- ❑ Providing financial support for stakeholders’ attendance at international meetings (tax incentives are given for participation in international standardization);
- ❑ Conducting surveys to identify current needs of industry; and
- ❑ Carrying out regular promotional events.

The government commitment at the strategic level can be seen in many of the milestones in the development of the quality infrastructure. Future developments are contained within the National Standards Strategy and Action Plan (NSSAP), which was endorsed by Government in October 2004. NSSAP provides for:

- ❑ Strategic involvement in regional and international standardization activities; and
- ❑ Enhancing stakeholder participation and support for standardization at regional and international levels.

The reasons for the positive evolution of the Malaysia quality infrastructure can be ascribed, among others, to:

- ❑ The tangible government commitment to enhancing the quality infrastructure in support of the Malaysia Vision to be recognized as a developed nation by 2020, including the enhancement of its position as a global player in the international markets.
- ❑ The rising awareness of all stakeholders on the importance of SCAM (standards, certification, accreditation and metrology) in Malaysia.

## Costa Rica

The quality infrastructure in Costa Rica has had to be re-engineered quite appreciably in recent years because it could not provide authorities and especially industry with the support required in export markets. The re-engineering was marked by five specific phases: confusion, ivory tower, breakdown, redesign and then recognition.

*'If technical regulations are not well prepared or are badly established, it is very difficult to comply or to demonstrate compliance. Technical regulations must be defined properly. This is the weakest point in Costa Rica's national quality system.'*

Juan María González Vásquez, SEYMA, Costa Rica

**Confusion.** The lack of knowledge, and low level of information and understanding about new practices and rules developed by others resulted in a low level of confidence. The existing infrastructure did not have the capacity to respond, leading to fear and frustration.

**Ivory tower.** With a view to strengthening the infrastructure, a high level of public intervention was deemed to be necessary. A new technically integrated and centralized institution with a special budget responsible to the ministry was established. Unfortunately only a few people had sufficient knowledge to make it work and a deep separation between the public and the private domain ensued. The control mechanisms were likewise steeped in bureaucracy, ultimately proving to be insufficient.

**Breakdown.** It was inevitable that this centralized approach would eventually break down as the budget increased, the number of public officials involved increased, and cases of failure came to light. This led to some serious introspection during which the help of international experts was sought. It was clear that the whole infrastructure had to be re-engineered from basic principles in spite of the resistance to change from the officials.

**Redesign.** During the redesign of the quality infrastructure, a new vision was proposed as well as a new institutional framework. The private sector was included in this exercise right from the start in order to deal with its needs. International best practices were used to benchmark the process. This resulted in the sharing of common experiences among the public and private sectors, enhanced cooperation and facilitated the evolution of a shared strategy.

**Recognition.** The redesign provided a basis for future development and growth and facilitated international participation. By adopting proper and efficient schemes, the growth in capacity of the infrastructure was considerably enhanced.

The quality infrastructure was established at three levels as indicated in the table below.

1st level	2nd level	3rd level
CONAC (National Board of Quality)	Standardization – INTECO	Standard technical committees
	Accreditation – ECA	Accreditation technical committees
	Metrology – LACOMET	Testing and certification bodies Calibration laboratories
	Technical regulations – ORT	Market surveillance
The Council provides overall policy direction for the whole system.	Bodies having responsibility for the basic building blocks of the quality infrastructure	Many organizations providing conformity assessment and standards related services, some on a commercial basis to industry and the authorities

The responsibilities of the various players were clearly identified, and there is an overall strategy-making or policy-making body comprising representatives of the public and private sectors.

The main lessons learned during the re-engineering exercise in Costa Rica were that the system will not be functional when the public sector does not have a dialogue with the private sector. In addition, it is far better to redesign the whole system from basic principles and implement a radical change, than to ‘tinker’ with an established infrastructure and organizations that will resist changing anyway.

## Benin

One of the major export commodities of Benin is shrimps, with exports of about 1000 tonnes a year to the European Union. The turnover of the enterprises involved in these exports amounts to about 5.5 million euros per year. Benin made the agonizing decision to voluntarily suspend exports to the European market in July 2003, because the government of Benin could not guarantee the conformity of seafood products in accordance with the latest European Directives. This suspension was effective for 18 months during which Benin sought help from international agencies in solving the problem. This situation put four processing factories dealing with fishery products on a tightrope and caused inconvenience to 30,000 fishers.

Funded by the EU and Germany, a programme to develop the quality infrastructure and capacity in the fishing industry to ensure that any future exports would meet the EU Directives was implemented. The programme was managed by UNIDO in cooperation with PTB (Germany). The outcome of the programme was

- Two laboratories were provided with the appropriate testing equipment;
- Training of the inspection staff of the Department of Fisheries;
- Building of capacity in the enterprises; and
- Strengthening of the standardization body.

All in all about 30,000 people were trained, including the fishers. The project cost 4.0 million euros, of which the EU and Germany provided 80% and the government and the private industry of Benin shouldered the remaining 20%. The self-imposed suspension was lifted in February 2005.

Even though the decision was a tough one to make, by taking the decision Benin opened the way for the international community to provide the required support. At the same time Benin protected its image as a serious supplier within its major market, the European Union. This stands in stark contrast to the experience of the Lake Victoria industry, as shown in appendix I.

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## Conclusion

An appropriate national quality infrastructure is crucial to successfully compete at the global level. It is necessary to provide confidence in the integrity or quality of products and services that are being exported to especially developed economies but also to developing countries. There is no magic formula. The way it is set up, the linkages within the national entities making up the quality infrastructure, their way of doing business, may differ from country to country. Yet the indicators of successful quality infrastructures have started to become clearer and clearer over time. Strategy-makers and decision-makers from developing countries and transition economies thus have ample opportunities to set up a quality infrastructure or to upgrade the existing one in accordance with their strategic priorities and existing resources. But they will have to give some time and thought to selecting the infrastructure elements and the precise organizational structure most conducive to their specific circumstances and commercial prospects.

*‘The challenge ahead is not to resist globalization and liberalization but to face them. We as developing countries have to prepare ourselves from now on to face the changing trading environment by working together to strengthen our quality infrastructures, our human resources base and R&D capacity to ensure competitiveness and access to international markets.’*

K. Palasuberniam, Assistant Director Export and Certification Section,  
Crop Protection and Plant Quarantine Division,  
Department of Agriculture, Malaysia

This paper has endeavoured to provide insight into the emerging international best practices, augmented by positive experiences of developing countries in this regard. The information is certainly not exhaustive and the future will still hold a number of surprises as developing countries and transition economies establish systems that are outside the current paradigm established mainly by developed countries. Developing countries should not be afraid to challenge current thinking.

Future guidance should be continually sought in the results of developing countries that have successfully implemented viable structures. There are no standard formulas; it is not a strict science. What works once may work again, but it may also have to be ‘tuned’ to another set of realities in another country.

We encourage decision-makers and strategists to continue to inform us and other network participants of their experiences. In this way we may be able to continually refine our guidelines and generate more concrete ideas on what represents ‘best practice’. And in this way, ITC’s Executive Forum should be able to facilitate and expedite effective decision-making on national quality infrastructure design and management.



## Appendix I

# The Lake Victoria fish exports

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### Situation before

A major fish industry had developed around Lake Victoria, shared by the United Republic of Tanzania (51%), Uganda (43%) and Kenya (6%), with revenues from fish exports amounting to over \$200 million per year. Over half a million people were earning their living from the fishing and processing of Nile perch from the lake and local supplier companies were also deriving considerable benefits from the fish industry. In 1999, after suspected fish poisoning, an EU export ban was imposed on Lake Victoria fish.

The three countries – in particular the United Republic of Tanzania and Uganda – suffered a tremendous loss. Fish exports from Uganda alone dropped dramatically by 50% in value between 1996 and 2000 and exports from the United Republic of Tanzania fell by almost the same level in 1999. In addition to the lost export earnings, one-third of some 200,000 people employed in the fishing industry lost their jobs. Fish factories either closed or were operating at as little as 20% capacity.

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### Situation after

The EU ban on Lake Victoria fish was lifted on Kenya, the United Republic of Tanzania and Uganda by the end of 2000. Fish exports from these countries not only regained its EU market share, but also gained access to the United States market after the establishment of a more reliable fish safety assurance system and the introduction of HACCP in particular.

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### The programme

Improvement of the Lake Victoria fish production chain was achieved through an integrated corrective action approach as well as through synergy between three UNIDO programmes and combination of efforts with partners such as:

- Uganda National Bureau of Standards;
- Tanzania Bureau of Standards;
- Federation of Kenya Employers;
- Lake Victoria Fishers Cooperative; and
- UNDP, WHO, FAO and DfID.

The programme lasted three years and cost \$4.6 million. Support was provided by Austria, Denmark, Germany, Italy, Japan, the United Kingdom, UNDP and UNIDO. In parallel, steps were taken to:

- ❑ Improve the organizational and regulatory framework for the industry;
- ❑ Strengthen the capacities of fish inspection services, technical support institutions; and
- ❑ Strengthen the capacities in the private sector – at all stages of industry from fishing to factory.

This was achieved through training of a critical mass of 50 GHP (good hygiene practices), HACCP (hazard analysis critical control points) and ISO 9000 specialists and inspectors from all stakeholders, in-plant training of 950 staff from 17 factories, and open training in fishing, fish transportation, handling and packing practices.

Particular emphasis was placed on the establishment of and training in working tools, guidelines and methodologies (fish inspection manual, code of practice, inspection guides and record keeping, traceability, etc.)

The result of the holistic approach was that:

- ❑ Fish safety and quality assurance systems were dramatically upgraded at all levels of the production chain;
- ❑ The role of central regulatory authorities was strengthened and their activities streamlined;
- ❑ A fish inspection system was implemented in accordance with international requirements;
- ❑ Technical support institutions were enhanced with newly formulated working guidelines and tools;
- ❑ National experts were properly trained in GHP and HACCP;
- ❑ HACCP systems were implemented on boats, landing sites and in processing plants to ensure safety of exported fish products; and
- ❑ Testing laboratories were internationally recognized.

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## The lessons learned

The major lessons learned during the development and implementation of the project were that:

- ❑ The establishment of QMS and HACCP systems was essential for restarting fish export;
- ❑ Strengthening of local support institutions such as standardization bodies and testing houses, inspection and certification bodies was decisive to regain the EU market and get access to new markets; and
- ❑ GHP was indispensable to upgrade technical skills of the fish processing plants and support institutions.



## The finances

The financial figures provide ample evidence of the success of the project.

<b>Losses</b>	<b>Figures</b>
Export earnings	\$36 900 000
Income of fishing community (\$850 000 per month) due to reduced prices and fishing activities	\$ 4 250 000
Factories that closed down	3 out of 11
Factories that reduced their labour force by 2/3	8 out of 11
Jobs lost in fish factories (1/3)	2 000
Jobs lost in fishing activities (1/3)	32 000
People who lost 2/3 of their income	68 000
Affected family members and relatives living on the same income	300 000

<b>Year</b>	<b>Income in \$</b>
1992	12 000 000
1996	60 000 000
January to March 1999	17 000 000
<b>After the EU ban</b>	
April to July 1999	2 500 000
<b>Project costs</b>	
Three year total	4 600 000
<b>After the EU ban was lifted</b>	
September to December 2000	7 995 000

(Compiled from UNIDO sources)

## Appendix II

# The cost and return of compliance

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### Cost of compliance

Studies that could provide a general picture of the cost of compliance that industry in developing countries face when exporting products to more developed economies are generally scarce. Useful models have nevertheless been employed by UNIDO and others that provide insight into some of the actual costs. A EUROMET publication<sup>1</sup> indicates that the associated costs of a decent measurement regime during production can constitute up to 10%-15% of the production costs. This money should be well spent and not wasted on technically unacceptable practices.

It is also complicated to obtain realistic estimates of the cost of compliance because it consists of costs of demonstrating compliance with requirements and costs of meeting requirements. The former can be readily calculated, whereas the latter is much more difficult, depending on the state of the industry.

As shown in the example in the box below, for 50 companies to export shrimp to the Netherlands, the total cost of demonstrating compliance would be \$9.25 million per year (or 2.3% of the total market value of the products) if all of it were outsourced. By developing a national capability (which would cost \$5.4 million) these costs could be reduced by about 30% or \$2.8 million per annum. By investing the \$5.4 million once, the country could save \$2.8 million every year on the cost of demonstrating compliance of the shrimps, thereby becoming more competitive. This does, however, usually mean that the authorities will have to take the lead in investing the resources, even if they negotiate and obtain support from the many donor agencies involved in this field. This calls for political will and a strategic decision!

The cost of meeting requirements could require an investment as large as \$120 million to \$150 million, or about 30%–35% of the value of the shrimp shipments! Once the systems have been established, the maintenance costs come down appreciably. As these amounts are significant, this is where industry often falters and thus some sort of government support will usually be required. The strategic decisions the developing country authorities would have to make would therefore have to be informed by this type of financial information. In addition, measures would have to be implemented to establish an infrastructure that is viable over the long term. Once again, *one size does not fit all!*

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<sup>1</sup> *Metrology – in Short*, EUROMET project 595, ISBN 87-988154-0-7.

### Cost of compliance

#### The case of shrimp exports to the Netherlands

The export of 100,000 tonnes of shrimps to the Netherlands would be subject to regulatory safety and health requirements (e.g. maximum pesticide residue levels, heavy metals, pathogenic micro-organisms) irradiation and packaging requirements. In addition, the market sets additional requirements, such as HACCP, ISO 14000, ISO 9000, SA 8000, International label for fish from the Marine Stewardship Council, and Environmentally Sound Production (ESP). The cost of compliance for the export of shrimp to the Netherlands by 50 companies would attract the following typical costs.

REQUIREMENTS TBT/SPS	Type of tests	No. of tests	Cost of tests	Cost per test	Total cost of testing
	Certificate	Certifications Xn	Outsourced \$C out	Domestic \$C dom	Out. and Dom. (\$C.Xn) ('000)
Additives and flavouring	Chemical	20 000	25	16	500 and 320
Cadmium, lead, mercury	Chemical	20 000	90	35	1 800 and 700
PCBs and PCTs	Chemical	20 000	120	96	2 400 and 1 920
Contaminants in food	Chemical	20 000	60	45	1 200 and 900
Maximum residue levels	Chemical	20 000	120	87	2 400 and 1 740
Packaging: GMP, Pack.	ISO 14001	50	8 000	6 200	400 and 310
Social market req.	SA 8000	50	3 000	2 300	150 and 115
Quality related mkt req.	ISO 9001	50	4 000	3 000	200 and 150
Environ. sound prod.	HACCP	50	4 000	3 000	200 and 150
<b>Total annual cost</b> for 50 companies to export 100 000 tonnes of shrimps				<b>Outsourced</b>	9 250 000
				<b>Domestic</b>	6 305 000

To establish a national quality infrastructure capable of providing the required services would be \$5.4 million. Additional issues would be the effort required to have the national infrastructure recognized in the Netherlands. The cost of implementation of all the management and quality related systems in the 50 companies is even more difficult to quantify. It can, however, be accepted that these costs would be a multiple of the certification costs of \$950 000 (or \$725 000 domestic). Some would suggest as high as 30 times!

(Adapted from UNIDO)

## Appendix III

# The Executive Forum's Consultative Cycle 2005

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### A STRATEGIC APPROACH TO THE QUALITY ASSURANCE CHALLENGE

Shah Alam, Malaysia  
27 – 30 June 2005

### The Programme

#### DAY 1 Monday, 27 June 2005

##### Session 1

09.00 – 09.30 Welcome and introductions

**Co-hosts:**

Mr. Shyam Gujadhur, Senior Adviser,  
Standards and Quality Management, International Trade Centre

Dato' Dr. Mohd. Ariffin Hj. Aton, President and Chief Executive Officer,  
SIRIM Berhad

##### Session 2

09.30 – 11.00 Export competitiveness and quality infrastructure: The need for a strategic response

**Focus:**

- i) To what extent are quality requirements increasingly shaping international commercial prospects for developing/transition economies?
- ii) What is the ideal quality infrastructure at the national level?
- iii) What are the cost implications?
- iv) What should be the key concerns of the national export strategy-maker?

**Session moderation:** Mr. Martin Kellermann, International Consultant (Standards, Technical Regulations and Conformity Assessment), South Africa

**Presentations:** Mr. Lalith Goonatilake, Senior Industrial Development Officer, Industrial Promotion and Technology Branch, UNIDO

Mr. K. Palasuberniam, Assistant Director, Export and Certification Section, Crop Protection and Plant Quarantine, Department of Agriculture, Malaysia

**Questions, answers and moderated debate**

**Session 3**

- 11.30 – 13.00     **Quality infrastructure: From optimal to possible**
- Focus:**
- i) Given limited resources, what options are available to developing countries/transition economies to building an appropriate quality infrastructure?
  - ii) What elements of the quality infrastructure could be handled at the regional level?
- Session moderation:** Mr. Shyam Gujadhur, Senior Adviser, Standards and Quality Management, International Trade Centre
- Panel discussion:** Mr. Parama Iswara Subramaniam, Senior Manager, Quality Management System Certification, SIRIM QAS International
- Mr. Ulrich Diekmann, Technical Cooperation Africa, Near-East and South-East Asia, Physikalisch-Technische Bundesanstalt (PTB), Germany
- Mr. Martin Kellermann, International Consultant (Standards, Technical Regulations and Conformity Assessment), South Africa
- Questions, answers and moderated debate**
- 14:30 – 17:00     Visit to SIRIM Berhad
- i) Overview of SIRIM. Visit of the Gallery, Testing Labs and the SIRIM Information Service
- 20:00             ITC-SIRIM Reception Dinner and Cocktails  
Saloma Bistro, Kuala Lumpur
- Departure by bus at 17:30

**DAY 2     Tuesday, 28 June 2005****Session 1**

- 09.00 – 10.30     The information gap
- Focus:**
- i) What information is essential (technical regulations, SPS measures, and standards and conformity assessment procedures)?
  - ii) How best to obtain this information and keep track of developments in target markets at the level of the commercial buyer?
  - iii) What are the respective roles of the public and private sector in information tracking, acquisition and dissemination?
  - iv) Should developing and transition economies participate in the development of international standards? If they do, how? If they don’t, what are the consequences?
  - v) What are the implications for the national approach to building a quality infrastructure?
- Session moderation:** YBhg. Datuk Merlyn Kasimir, Chief Operating Officer, Malaysia External Trade Development Corporation (MATRADE), Malaysia
- Presentation:** Mr. Rajinder Raj, Senior General Manager, Standards Management Department, SIRIM Berhad
- Questions, answers and moderated debate**

**Session 2**

11.00 – 13.00

**The key issue: Confirming compliance****Focus:**

- i) How to facilitate companies demonstrating compliance?
- ii) How to ensure acceptance in the target market?
- iii) How do developing countries best respond to the increasing demands for traceability of measurements?
- iv) What are the strategic implications of a new emphasis on traceability requirements relating to food products?
- v) What are the implications for the national approach to building a quality infrastructure?

**Session moderation:** YBhg. Dato’ A. Aziz Mat, General Manager, SIRIM Berhad, Malaysia

**Presentations:** Mr. Shyam Gujadhur, Senior Adviser, Standards and Quality Management, International Trade Centre  
Mr. Wolfgang Schmid, Presidential Staff Office, PTB, Germany

**Questions, answers and moderated debate**

14:00 – 17:00

Visit to a company using SIRIM services

- i) Visit to Khind-Mistral Industries Sdn Bhd, Sekinchan, Selangor, Malaysia

**DAY 3      Wednesday, 29 June 2005****Session 1**

9.00 – 10.00

**Enabling compliance****Focus:**

- i) What programmes should be put in place to enable compliance?
- ii) What are the keys to success of these programmes?
- iii) What are the implications for the national approach to building a quality infrastructure?

**Session moderation:** Dr. Mohd Azman Idris, General Manager, Standards and Quality Industry Services Department, SIRIM Berhad, Malaysia

**Presentation:** Mdm Khalidah Mustafa, Principal Consultant, Standards and Quality Industry Services Department, SIRIM Berhad, Malaysia

**Questions, answers and moderated debate****Session 2**

10.30 - 12:30

**Innovative strategies and country approaches****Focus:**

- i) What are the specific roles and responsibilities of the public and private sectors, as well as of the national trade support network, in setting-up and maintaining a relevant, functioning quality infrastructure?
- ii) What should be the key concerns of the national export strategy-maker?

**Session moderation:** YBhg. Dato’ A. Aziz Mat, General Manager, SIRIM Berhad

**Presentation:** The South African approach: Responding to competition – Restructuring quality infrastructure.

Mr. Martin Kellermann, International Consultant (Standards, Technical Regulations and Conformity Assessment), South Africa

**Presentation:** The Malaysian approach: Evolution towards international recognition

Mdm Mariani Mohammad, Director General, Department of Standards, Malaysia

**Presentation:** The Costa Rican national quality system: Responding to WTO requirements

Mr. Juan María González Vásquez, SEYMA, Costa Rica

**Presentation:** The experience of Benin: Responding to the quality assurance challenge

Mr. Henri Jean-Claude Gouthon, Entrepreneur, Benin

**Questions, answers and moderated debate**

13:30 – 17:00

Visits to companies and quality infrastructure organizations

ii) Visit to the Malaysian Palm Oil Board, Bangi, Malaysia

ii) Visit to the Malaysian Government Administrative Centre, Putrajaya, Malaysia

## **DAY 4 Thursday, 30 June 2005**

### **Session 1**

09.00 – 10.15

#### **Quality infrastructure - Emerging issues I**

Management system standards (ISO 9001 and 14001, OHSAS 18001, SA 8000 and HACCP) for exporting enterprises: the moving goal posts

**Session moderation:** Mr. Shyam Gujadhur, Senior Adviser, Standards and Quality Management, International Trade Centre

**Panel discussion:** Mr. Parama Iswara Subramaniam, Senior Manager, Quality Management System Certification, SIRIM QAS International

Mr. Abdul Aziz Long, Senior Manager, Environmental Management Systems Certification, SIRIM QAS International

Mdm Norafiza Saim, Senior Manager, Occupational Health and Safety Systems Certification, SIRIM QAS International

Mr. Teruo Kawamura, Senior Expert on Business Excellence, Japanese Standards Association (JSA)

**Questions, answers and moderated debate**

### **Session 2**

10.45 – 12.00

#### **Quality infrastructure – Emerging issues II**

Quality management in the services sector

**Session moderation:** Mdm Catherine Lee Fay Foon, Director of Quality Policy and Management Division, Malaysian Administrative, Modernisation and Management Planning Unit, Prime Minister’s Department, Malaysia

**Presentation:** Mr. Martin Kellermann, International Consultant (Standards, Technical Regulations and Conformity Assessment), South Africa

**Questions, answers and moderated debate**

**Session 3**

12.00 – 13.30

**Quality and security**

Emerging issues concerning security-related quality requirements:  
Scope and response requirements

**Session moderation:** Mdm Azizah Hamzah, Director of ICT Policy Division,  
Ministry of Science, Technology and Innovation, Malaysia

**Panel discussion:** Mr. Ariffuddin Aizuddin, Manager, Security Management &  
Implementation Division, National Information Security and Emergency  
Response Centre, Malaysia

Dr. Nah Soo Hoe, Malaysia National Computer Confederation

**Questions, answers and moderated debate****Session 4**

14:30 – 16:00

**Conclusions, lessons learned and follow-up**

Session moderation: Mr. Shyam Gujadhur, Senior Adviser, Standards and  
Quality Management, International Trade Centre

16:00 – 16:30

**Closing**



## Appendix IV

### List of participants

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