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National Metrology Institute

INTERNATIONAL COOPERATION

The Answer to the Global Quality Challenge: A National Quality Infrastructure

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DEUTSCHE ZUSAMMENARBEIT

On behalf of

Federal Ministry
for Economic Cooperation
and Development

On behalf of the Federal Government of Germany, the Physikalisch-Technische Bundesanstalt promotes the improvement of the framework conditions for economic, social and environmentally friendly action and thus supports the development of quality infrastructure.

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Annexes

Forewords

Foreword by: Ambassador Alfonso Quiñónez,
Executive Secretary for Integral Development Organization of American States

The purpose of this publication is to assist private and government entities that are called upon to play an important role in the establishment of a coherent and effective National Quality Infrastructure, in accordance with internationally agreed parameters. It should also be a guide for enterprises, particularly small and medium sized, to the steps that have to be followed in order for their products and/or services to fulfill the quality requirements demanded by international markets.

Quality is the result of the integration and coordination of a series of activities in several interrelated subjects: metrology, standardization, testing, accreditation, and certification.

For several years, many organizations and cooperation agencies have worked together with the OAS on those subjects, and the results of these varied experiences have brought about the synergy presently called National Quality Infrastructure

The main purpose of this new concept in the search for Quality is to follow a logical process, starting with measurement and up to certification of products and services, a certification that can take the form of a seal of quality. This seal of quality is a guarantee that the specifications declared by the producer and the requirements of the consumer (market) are both fulfilled. A third independent authority is in charge of accreditation and this accreditation is what makes trustworthy the certifications, and thus the quality.

Quality certification, together with the price of the products and services and the ways in which these are provided, guarantee competitiveness in national and international markets. Through competitiveness, enterprises can maintain their national markets. On the other hand, access to new markets allows enterprises to expand. Expansion helps create new jobs and higher economic incomes. This in turn contributes to the fight against poverty and drives to higher technological, economic and social development so the countries can start or continue on the road to achieve greater competitiveness and a better quality of life based on a National Quality Infrastructure.

Improvement of the quality of life in its member states is the main objective of the Organization of American States. For this reason, the OAS is actively engaged in promoting the development of National Quality Infrastructures. This can be only achieved through coordination and cooperation of the specialized regional bodies of the hemisphere such as SIM (Inter-American Metrology System), IAAC (Inter American Accreditation Cooperation), and COPANT (Pan American Standards Commission), among others, in order to allow and promote effective sharing and dissemination of knowledge and experiences as well as the efficient use of available resources.

The resulting continuous dialogue will also foster regional integration efforts – a key condition for sound hemispheric development and prosperity.

Foreword by: Patricia Francis, Executive Director, International Trade Centre

There has been a significant reduction in tariff barriers following the Uruguay Round of Trade Negotiations. However, there has been a considerable increase in non-tariff barriers, whether in the form of official standards or private standards, which pose serious challenges, especially to exporters in developing countries and economies in transition. The problem these exporters face is that technical regulations and sanitary and phytosanitary measures in export markets are based on international standards which were established without their inputs and therefore do not reflect the views of all stakeholders.

Therefore, there is first the lack of understanding about the requirements and secondly a lack of financial and human resources to establish an adequate national quality infrastructure which is compliant with technical requirements in export markets.

The International Trade Centre, under its Executive Forum programme which brings together senior decision-makers in the public and private sectors to deliberate on issues related to export strategy, organized a consultation in Malaysia in 2005 to deliberate upon how to tackle the challenges faced by exporters in developing countries and transition economies for meeting the stringent technical requirements of developed countries. This resulted in ITC publication on "Innovations in Export Strategy: A Strategic Approach to the Quality Assurance Challenge". I am pleased to note that the present book provides an in-depth analysis of the complex issues facing countries in their endeavour to increase their exports and is a valuable component to our publications.

The book sheds light on the various elements of a quality infrastructure comprising standardization, metrology, testing, certification and accreditation. It emphasizes the need for a national quality infrastructure to overcome the challenges faced by countries in meeting the requirements of export markets and how such an infrastructure can help not only producers but regulators and consumers as well. I am confident that the book will stimulate decision-makers in developing and transition economies to bring clarity to the decisions necessary to establish and strengthen their national quality infrastructure so that they meet international requirements and facilitate exports from their countries.

Foreword by: Prof. Ernst O. Goebel,
President of Physikalisch-Technische Bundesanstalt, Germany

Quality has always been an important issue, and numerous publications have appeared on this subject in the past in all parts of the world. Since, however, the spirit of globalisation has been blowing throughout the world and has triggered an immense exchange of products and services, a new perspective has emerged. Aspects of quality must now be transformed from subjective perceptions into worldwide marketable and negotiable objective criteria which are then, in international and regional standardisation, metrology or accreditation organisations, converted into consensus-capable standards. In these organisations, the corresponding structures for a harmonisation and mutual recognition are established; this, to a large extent, gives equal status to all players in worldwide trade. As head of a national metrology institute, I am aware of the great challenge national policy makers are facing when adapting the quality infrastructure of a country to harmonised criteria and international requirements.

To enable also small national economies with limited resources to master this challenge, it is necessary – instead of developing many separate quality services – to create a joint national concept for an internationally recognised quality infrastructure, a concept which does not aim for the highest technical level but is rather tailored to the needs of the respective users.

The present book conveys precisely this systemic approach, by combining technical expertise with many years of experience gathered in the field of technical cooperation. The main focus is placed on elucidating the interactions between the different components of the system (standardisation, metrology, testing, certification and accreditation) within the national and international context, whereby each component will – to the extent necessary for the layman's understanding – also be described separately.

Part 1 – Introduction

In this book we try to show how a national quality infrastructure, QI, relies on five main components, how these are related between themselves and how, in turn, the national infrastructure relates to the international quality system.

Part 2, Why a National Quality Infrastructure, analyzes the current global challenge from the point of view of quality, and how a national quality infrastructure can help producers, regulators and consumers face this challenge.

Part 3, National Quality Infrastructure – Summary and context, is a technical summary on the QI components, their inter-relationships, and their integration into the international quality system, as well as the impact of such an infrastructure on the value chains[1] and as a technical arm for regulators.

In **Part 4, The five technical components of the National Quality Infrastructure,** each one of the five components – standardization, metrology, testing, certification, and accreditation – is analyzed in detail.

Part 5, Integration of the components into a National Quality Infrastructure (systemic approach), recapitulates briefly the importance of each component from the point of view of a producer wishing to obtain a certificate of quality.

Part 6, A case of application of a National Quality Infrastructure to a productive chain, is a more detailed example of how each component of the QI can help a producer – in this case a shrimp farm – to work within internationally approved quality parameters, and be able to demonstrate world-wide this compliance.

Finally, **Part 7, Recommendations,** touches very briefly on aspects such as characteristics of the legal background, voluntary and mandatory aspects, the functions and use of the QI by regulating bodies, participation of the public and private sectors, alliances and networks, and international recognition.

1 We will be using the term "value chains" indistinctly for value chains, productive chains, or supply chains.

The authors wish to thank the many organizations and individuals who have contributed. In particular, we wish to thank the Bureau International des Poids et Mesures – BIPM, The International Accreditation Forum – IAF, The International Laboratory Accreditation Cooperation – ILAC, the International Organization for Standardization – ISO, the Organisation Internationale de Métrologie Légale – OIML, the World Trade Organization – WTO, for their kind authorization for the use of their logos and of material taken from their website[2]. Also to the Asian Development Bank – ADB, the Institute of Development Studies – IDS, Taylor and Francis Journals, UN Millennium Project, Dr. Stefano Ponte, for their permission to use material from their publications.

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Part 2 – Preface

Industrial countries rely on many standards and technical regulations for their trade-related activities. If developing countries wish to enter the global market, they must be able to count on standards-related facilities including access to standards and technical regulations, metrology, testing, quality assessment, certification and accreditation.

These elements are the components of what we call a National Quality Infrastructure – QI. Current global trade is based mainly on technology-intensive manufactured goods, not raw materials. Each and all of the QI components are essential to production and trade, and they are closely related. There cannot be a sound QI and thus a sound basis for global trade, without each and all of them, even though they may exist at different degrees of development.

If developing countries want to attract foreign investments, they must keep in mind that infrastructure – and this includes quality infrastructure – is one of the key factors foreign investors will consider.

In the case of a national quality infrastructure, they must at the very least: ensure access to international standards and technical regulations, guarantee reliable measurements, and set up a system that will allow accreditation of their testing and certification facilities in such a way that the results of these bodies will be internationally accepted. A QI also supports local industries and consumers. In most cases, the countries have to enforce standards and technical regulations that conform to international requirements. For instance, when exporting agricultural and food products, it is necessary as a minimum to demonstrate compliance with international sanitary, phytosanitary and safety standards. Other specifications must also be met such as those related, for example, to packaging and labeling.

Measurements must be reliable and traceable to international measurement standards so that measurements and tests for production, quality and certification activities are correct. This requires laboratories for physical measurement standards and for certified reference materials in chemistry, as well as legal and industrial metrology and a system for calibration.

Because sending samples abroad is unsuitable economically, products and processes should preferably be tested locally, according to methods accepted internationally and at laboratories that meet international evaluation criteria.

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A certification and conformity assessment system is essential. In addition to assessment of conformity with standards and technical regulations, in many cases international trade may require certification to ISO 9000 (quality systems), ISO 14000 (environmental management system), HACCP (Hazard Analysis and Critical Control Points).

The different quality certifications of products, systems and processes issued by local certification bodies must be accepted by other countries, either through mutual recognition agreements or through some system of accreditation by internationally recognized accreditation entities.

A QI can help ensure legitimate compliance with health, safety and environmental concerns for export purposes but also for internal consumption towards the wellbeing of the population.

The following chapters will consider one by one: the need for recognized quality, the characteristics of each element that goes into such a recognized quality, the integration of these components into a National Quality Infrastructure and its relation to the international quality system currently in place.

2.1. Why a national quality infrastructure?

As long as international trade was limited and manufacturers and suppliers came from the same economic zone, no driving force existed to harmonize standards and measuring units. Nowadays, the impacts of the steady growth of global trade are more and more visible and many firms and industries now have organizational structures that extend across national and regional borders. This has led to the formation of truly global-scale economic systems; today, the process of economic development cannot be isolated from these global systems [15].

Industrialized countries have had centuries to improve and come up with functioning metrology, standardization, testing and quality management systems (known as MSTQ or similar abbreviations). By proving their technical competence through several means of evaluations and comparisons, they have achieved multilateral recognition.

In contrast, to compete with their industrialized counterparts, developing economies have to catch up fast in all relevant fields of export requirements, food safety, consumer protection or health issues. However, a realistic view shows in many countries a fragmented and uncoordinated system, with unclear responsibilities, either accepted only for certain components on a bilateral basis, periodically inspected and supervised by the importing country, or simply not recognized internationally [28].

What is a quality infrastructure? Metrology, standards, testing and quality management are vital to products and product processes although consumers are not always aware of it. Yet these same consumers often use quality marks from product certifiers as a guide when making purchasing decisions. And their attention is drawn to the area in a negative way when, for example, technical equipment cannot be connected up abroad.

Quality infrastructure, QI, refers here to all aspects of metrology, standardization, testing, and quality management including certification and accreditation. This includes both public and private institutions and the regulatory framework within which they operate.

Clearly defined target groups are:

- Businesses and producers in agriculture, forestry, fisheries, crafts and trades who will benefit from a trade sector regulated by reliable QI services.
- Small and medium-sized enterprises that, unlike large companies, tend not to have any calibration or testing capacities of their own and can call on the support of central QI bodies. One key factor is that they are enabled to increase sales of their product by being able to provide proof of its quality.
- Domestic trade and export/import, which rely on testing facilities, e.g. for submitting to inspections or verification of quantity or quality.
- Regulators, who can rely on this infrastructure, thus avoiding duplicating facilities and services, particularly in countries with limited resources,
- Research and development in enterprises, as they will have better access to all components of quality assurance,
- Scientific and academic communities who are dependent on sound and internationally recognized measurements and testing procedures,
- Financial institutions who will be more inclined to grant credits to enterprises capable of showing quality certifications,
- Insurance companies who may offer higher premiums to those who comply with quality standards,
- Arbitration bodies in commercial disputes, both national and international.

The ultimate target group is, in fact, the entire population, because more competitive companies, greater integration into the world trading system, and improved consumer and environmental protection, have a positive impact on the labor market, income levels and quality of life [13].

2.2. Challenges from free trade and globalization

All countries should be enabled to enjoy the advantages of globalization while effectively protecting themselves from its risks [13].

Standards and their enforcement can mean new entry barriers. An example: in developing countries, expensive certification procedures mean that agricultural smallholders and cooperatives that do not have access to technical assistance are at a serious disadvantage. Public institutions are increasingly unable to defend the interests of producers, especially small-scale ones. The result is that, in many instances, small producers in developing countries have been completely cut off from the process of standard setting and monitoring [27].

Formerly, only tariffs were in principle recognized as restrictions to export/import and international trading. However, with the globalization of economies, the days when nations could afford to indulge in bilateral tariff-cutting negotiations have largely gone. Attention has shifted to so-called technical, or non-tariff, barriers to trade [7].

> The Agreement on Technical Barriers to Trade (TBT) – sometimes referred to as the Standards Code – is one of the legal texts of the WTO Agreement which obliges WTO Members to ensure that technical regulations, voluntary standards and conformity assessment procedures do not create unnecessary obstacles to trade [34].

A national quality infrastructure is essential in breaking down technical barriers to trade. It is thus the key to the greater integration of the partner countries into the international trading system [13].

For conscientious manufacturers and service providers, having their products assessed and certified as conforming to ISO International Standards allows them to distinguish themselves from less reputable suppliers. When public health, safety or the environment may be at stake, conformity assessment is usually made obligatory by government regulations. Without official assessment and approval, goods may be barred from sale, or suppliers disqualified from bidding for government procurement contracts [5].

Bilateral and multilateral free trade agreements make more and more reference to recognized technical competence through equivalent QI structures. For instance, the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) states clearly that Central Government Bodies shall ensure acceptance of conformity assessment procedures based on adequate technical competence and verified compliance through accreditations. This is a requirement that cannot be fulfilled without having an internationally recognized QI structure in place [28].

WTO – TBT Agreement, Article 6: Recognition of Conformity Assessment by Central Government Bodies – Article 6.1.1 requires:

- adequate and enduring technical competence ...
- confidence in the reliability of conformity assessment results ...
- verified compliance ... through accreditations ...
- with relevant guides and recommendations issued by
- international standardizing bodies ...

In addition to the requirements of the WTO committee on technical barriers to trade, known as TBT, another WTO committee, on Sanitary and Phytosanitary Measures – SPS, also imposes a series of requirements albeit specifying that "...sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade". These include aspects related to control, inspection procedures, quarantine treatment, etc., and compliance relies on a sound quality infrastructure [30].

> The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) sets out the basic rules for food safety and animal and plant health standards. It allows countries to set their own standards. But it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. And they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail [34].

Recent multilateral trade agreements, such as "DR-CAFTA – TBT" (the agreement on technical barriers to trade of the Dominican Republic and Central American Free Trade Agreement), are becoming even more specific in their requirements. For instance, DR-CAFTA specifies in a footnote that any reference to a standard, technical regulation or conformity assessment procedure includes those related to metrology [12].

There are nowadays several levels of compliance to be reckoned with:

- national laws on, for instance, safety and sanitary registers; they are considered a minimum for access to national markets,
- additional demands from national clients, such as supermarkets or any company that defines standards to be met by its suppliers; these are national market requirements,
- international laws such as EU directives, US FDA regulations, food safety regulations; these can be seen as minimum requirements for access to international markets and they may vary from one destination to another,
- additional individual demands from international clients such as international retailers (EurepGAP), global players, additional food safety standards.

Being able to fulfill all these requirements and demonstrate the corresponding compliance is a difficult and costly process, the more so for countries lacking a QI, one capable of immediate response to the needs of the private entrepreneurial sector. This requires at the very least, access to a **national standards organization**; it will support setting up standards, give access to existing standards and, more important, it can help entrepreneurs in the use of standards to meet the requirements set up by their national and international clients. A **national metrology institute** is another requirement; it is the custodian of the national measurement standards with their international traceability and it transfers this traceability to secondary and industrial measurement standards as well as eventually offering reliable calibration services at a reasonable cost. The third indispensable entity is a **national accreditation body**; its aim is to ensure the technical competence of laboratories, of inspection bodies, and of the quality certifications granted in the country [3].

A National Quality Infrastructure requires at least

Figure 1

It should however be noted that national schemes can be varied.

Ideally, there will be technical (not political!) bodies, totally independent and with entrepreneurial management. In fact, there exist several possible mixes of two and three functions in the same body. This can work when functions are strictly separated, that is when management is the only shared aspect and there is no political hierarchy. If not, independence and impartiality which are internationally required for recognition will never be attained. Following sections will deal further with this.

2.3. Innovation and competitiveness

The capacity for innovation is the capacity of enterprises and of a society as a whole to take advantage of knowledge and know-how in national and international markets [30]. Relatively recent examples of innovation are: transistor radios, credit or debit cards, and smart phones, all of which have resulted in dramatic changes in the habits and quality of life of millions of persons the world over.

> The invention of the credit card, introduced by Bank of America Corp. in 1958, has given countless people access to easy and immediate credit, and the possibility of international commerce [10].

An innovation doesn't necessarily have to be a technological breakthrough, like the Internet. It can be changes in the way things are done – such as "lean manufacturing", first introduced by Toyota, to increase the quality and reduce the cost of assembly-line production – or adaptations of existing ideas or techniques – such as "green" roofs built with a final layer of living plants and dirt or synthetic soil as insulation [6].

> In India, the "Jaipur foot", an artificial limb, allows Indians to comfortably squat, sit cross-legged, and walk barefoot, as is often their custom [6].

Developing countries should be focusing innovation in those areas that currently represent high import costs and/or high environmental damage, such as energy, fuels, transport, some uses of plastic, pest control, etc.

2.4. Access to international markets and preservation of domestic markets

Globalization means that participation in markets is more and more decided based on quality of the products and services, rather than on their price. In many enterprises competitiveness is often limited because their products, services and procedures do not comply with the minimum requirements for quality that are nowadays imperative in commercial transactions, national or international, particularly in regulated markets. This is valid for crafts, small and medium-sized enterprises, and it is partly due to the lack of information and a proper national quality infrastructure, working in accordance with international standards [3].

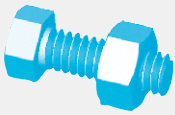
The services provided by several quality infrastructure institutions help boost competitiveness and allow production to be based on a division of labor. They are important for the establishment of regional markets, to allow goods to be traded internationally, and they are one of a range of instruments used to dismantle technical barriers to trade [13].

> Harmonizing conformity assessment procedures around the world has far-reaching benefits for international trade in general. Agreements among nations or regions on the mutual acceptability of requirements, assessment methods, inspection or test results, etc., can all help to reduce or remove so-called technical barriers to trade. These are procedures or requirements relating to importation and to market access that vary from country to country and may bar a foreign product [5].

A national quality infrastructure – QI, helps to promote sustainable development mainly through boosting the private sector by making companies more competitive.

To export, producers in the developing countries must meet the demands of the target markets in terms of quality, safety, reliability, environmental compatibility and hygiene and they must be able to provide credible proof of this. This is all the more true for agricultural products. A prerequisite is thus the existence of a quality infrastructure that meets international standards and that monitors the production chains and furnishes the proof required. If this infrastructure is not in place or if it is underdeveloped, the lack of acceptable proof can constitute a technical barrier to trade. Indeed, with the growing number of standards and technical rules imposed by the market and the ever higher demands, technical barriers to trade are becoming an increasingly important issue. Today, they represent a major obstacle to poverty reduction through trade [13].

Standardization of screw threads across countries solves what has been a major headache for manufacturers and product users [26].



In order to **create regional markets**, standardized regulations are required. National regulations and standards need to be harmonized or replaced by regional regulations and standards. At the same time, an acceptable national quality infrastructure needs to be built to establish the technical and administrative requirements for the testing and control of these standards. The process of expansion of the European Union is an example of how wide-ranging a process this is and how much time, advice and expense is involved [13].

Without the standardized dimensions of freight containers, international trade would be slower and more expensive [25].

For the **domestic market**, the national quality infrastructure has, amongst other things, a protective function. It provides the necessary structure for effective market monitoring and for **consumer protection.** To ensure fair trade, both imports and local production must be strictly submitted to the same rules; this protects domestic producers and at the same time provides incentives for their competitiveness. For this purpose, products, either imported or locally produced, are, for example, examined to ensure that they conform to safety regulations or for protection against hazardous characteristics. Quantitative measurements are also required (weight, volume, length) so as to protect the producer (often small farmers) or the consumer from being charged false prices and to create the necessary conditions for fair trade and, therefore, social justice [13].

Quality of life is affected when disabled persons find that dimensions of wheel-chairs and of entrances have not been standardized [25].

2.5. Consumer protection (health, safety, environment)

The national legislature is responsible for the definition of the desired level of protection of the country and its people. All regulations related to this protection should be harmonized as much as possible with regional and international recommendations; however, they must take into account the national technical quality infrastructure necessary for enforcement. These regulations must apply both to locally produced goods and services and to imports.

Consumers benefit from conformity assessment because it provides them with a basis for selecting products or services. They may have more confidence in products or services that bear a mark or certificate of conformity that attests to quality, safety or other desirable characteristics [5].

From the point of view of legal certainty and development of the legal system, technical regulations are required to identify the role of the statutory measuring and testing system and to make stipulations for business e. g. in terms of consumer protection, health and safety and environmental protection. These should be integrated into the economic and legal system.

Why is it necessary to strengthen the national quality infrastructure?
From the perspective of consumer protection, in the areas of:

- health,
- safety and food safety,
- environment.

Figure 2

For instance, measurements are a key daily feature of **medical practice** (body temperature, blood pressure, composition of the blood etc.). They are required for recognizing and treating illnesses and are used when making decisions on required therapies. False measurements and the resulting false decisions can, at best, generate additional costs and, at worst, can be harmful to health or even fatal.

As part of effective environmental and consumer protection, products and technical equipment that present a potential risk must be tested for **safety** by competent bodies, licensed by independent authorities in accordance with the appropriate technical regulations, and their use should be monitored (market access and monitoring).

Many current natural disasters such as droughts, floods, harsher hurricanes and tsunamis, are blamed on climate changes; the increase in the incidence of skin cancers has also been tied up to an increase in UV radiations due, at least in part, to damage to the ozone layer and this damage is attributed to increased pollution. For instance, we use up a lot of energy to cool us in summer and this results in warmer summers which then require even more cooling creating an endless spiral of consumption. Many regulations concerning the use of **natural resources** and the impact of human activities on the **environment** are tied to measurable parameters (e.g. regulations concerning consumption of resources, water and energy, and limits on the amount of pollutants emitted in waste gas and wastewater).

Controls must be carried out to monitor adherence to the relevant environmental standards, the standards must be developed or adapted and sanctions must be imposed for any non-compliance with the regulations. The QI establishes the necessary technical framework [13].

2.6. Assistance to regulators and mediators in carrying out their duties

In their function as protectors of consumers, environment, national territory, etc., regulatory bodies in ministries have to define technical regulations and supervise enforcement. They can be assisted in these functions by using the national quality infrastructure – which can include private entities such as a standards body, an accreditation body, testing and calibration laboratories, certifiers, etc. – as their technical arm for implementation of these regulations. This allows the concerned ministries to make better use of their limited resources by not duplicating trained personnel and laboratories when there is no critical mass to justify their continued existence with all its implications. They can concentrate on their core business to assure functioning of the system by managing it without necessarily having in place a technical infrastructure of their own.

Regulators benefit from conformity assessment which gives them a means of enforcing governmental health, safety and environmental legislation [5].

Mediators are the organizations at meso (middle) level, either regionally or in individual countries, such as:

- legal metrology institutions for consumer, health or environmental protection,
- calibration services – they provide the necessary services, particularly for small and medium-sized enterprises,
- national metrology institutes – they hold in readiness the national measurement standards in the country to be used as a reference, ensure that the right measures are passed on, and conduct international comparisons,
- standards organizations and information centers – they support the dismantling of technical barriers to trade, disseminate knowledge on international technical regulations and provide access to relevant sources; information is a must,
- testing institutes – they conduct professional and independent tests on products, such as foodstuffs, for the purpose of consumer protection,
- accreditation bodies – they assess the competence of certifiers and calibration and testing services, and thus provide an assurance of international acceptance for the certificates, these being increasingly required in such fields as management of quality, the environment, health and safety at work, and hygiene,
- quality associations – they collect know-how on the issues of quality and management systems, develop that know-how and offer their services as trainers and staff certifiers for the training of quality professionals,
- chambers of commerce and industry associations as representatives of industry – they can act as an interface between their members and other mediators and can also operate as multipliers through awareness-raising measures.

Beneficiaries and multipliers:
- legal metrology institutions,
- calibration services,
- national metrology institutes,
- standards organizations and information centres,
- testing institutes,
- accreditation bodies,
- quality associations,
- chambers of commerce and industry associations.

Assistance measures must be accompanied – and in some cases preceded – by activities at the higher political level. These are aimed at decision-makers who set the political and legal framework in the countries and regions [13].

2.7. Assistance to economic development

The national quality infrastructure – QI is to be seen as part of the whole requisite infrastructure of the country, with the same level of importance as roads and highways, schools, basic medical services, etc. Without a QI neither development nor competitiveness are possible. Adequate infrastructure is a necessary, if not sufficient, condition for enhancing the creation and application of science, technology and innovation in development [32]. The key concern should be to promote and assist small and medium-sized enterprises because, unlike most large companies, they usually do not have the capacity and resources to conduct all the necessary quality controls themselves and they must rely on external services [13].

Why is it necessary to strengthen the national quality infrastructure?
From the perspective of economic development:
For competitive products in

- national markets,
- international markets.

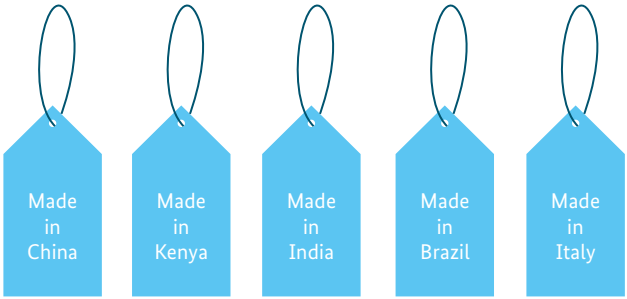


Figure 3

If producers wish to offer competitive products, those products must possess the properties prescribed in the normative documents of the target markets and they must pass the relevant tests. Often, there is insufficient knowledge of these requirements. It is all the more difficult to prove conformity with these standards and rules if the measuring and testing institutions are not in place or if the results are not recognized because tests were not carried out in accordance with international standards.

These deficiencies then continue at a higher level. A lack of relevant experience at the technical level makes it harder for developing countries to be involved in shaping international regimes. The vicious circle is then complete, because the interests of these countries are not properly taken into account. As a result, their competitiveness suffers as well as the diversification of their economies and their equal integration into the global economy.

MSTQ helps to promote sustainable development mainly by:

- paving the way towards further integration of the partner countries in the interests of a fairer global trade regime,
- establishing institutions and influencing the enabling environment at the national level.

Shaping the domestic environment for business and society so that it conforms to development objectives is a major task of the legislature. It is the task of the State to regulate matters relating to the applied system of measurements, the regulations and standards for the environment, health and safety, and the responsibilities of state and private organizations. States with efficient public structures – including a large number of quality infrastructure institutions – are better able to articulate the interests of their citizens in the framework of global policy-making, and to implement international regimes. Yet, not all tasks relating to the QI need to be performed by state bodies. By relieving the public administration of such tasks, capacities can be freed up for other tasks, the state can be encouraged to use public resources responsibly and the groups concerned are motivated to take the initiative [13].

2.8. Assistance to regional integration

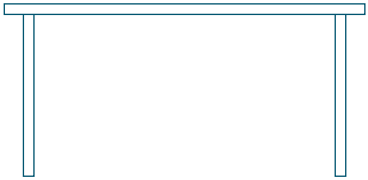
Assistance in the field of quality infrastructure also has a positive impact on **regional integration** processes. A dialogue focusing initially on technical issues can have a confidence-building impact. This can then foster closer contacts at the political level. The establishment of a fully formed national infrastructure of the necessary breadth and depth requires investment and ties up resources over a long period. For many countries, this is neither feasible nor useful. Regional cooperation can compensate for this, for example through agreements for the joint use of a complementary infrastructure or by strengthening dialogue between experts. As a result, support of this kind can help with the development of regional economic areas. As an example, thanks to the harmonization of European directives, the European Union has a single Enquiry Point and a single Notification Authority for the SPS Agreement.

Conversely, a structure solely at regional level, as a replacement for autonomous national structures, has proved in the past to be inadequate.

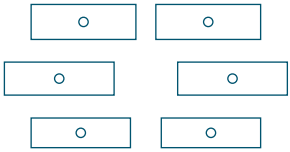
So that the desired improvements are maintained when foreign assistance measures have come to an end, it should be borne in mind that continuity and sustainability are of vital importance in the establishment of quality infrastructures [13].

Part 3 – Quality Infrastructure – Summary and Context

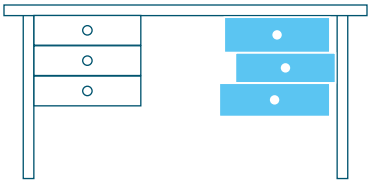
The system of **industrial production** based on the division of labor and the **international exchange of goods** and **commodities** demand that materials, components and manufacturing processes should conform to a given, specified quality.



Company A manufactures desks without drawers



Company B manufactures only drawers



This result ...

Figure 4

Or this result!

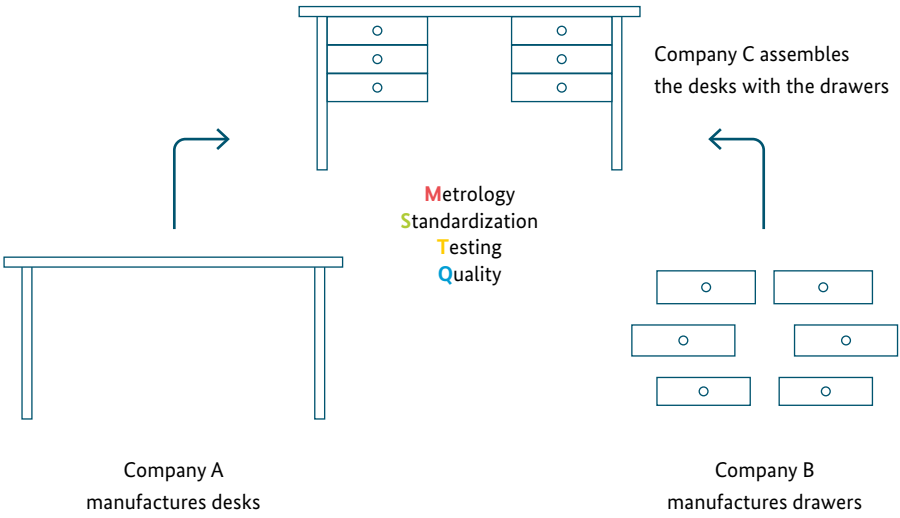
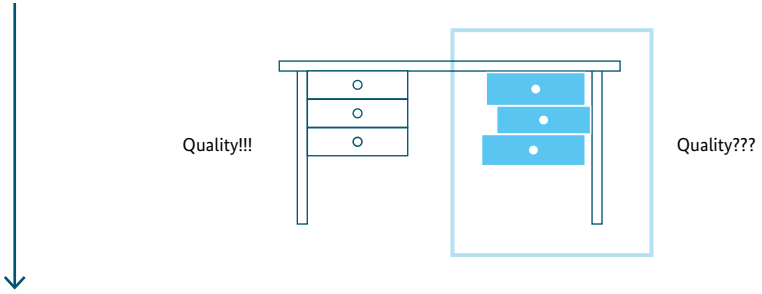


Figure 5

Standardization = Definition of properties, dimensions, tolerances
Metrology = Guarantee of exact and reliable measurements
Testing = Analysis of properties, ingredients, characteristics, etc.



Quality Management = Reliable application of quality standards
↳ Certification = Conformity with requirements defined in standards
↳ Accreditation = Recognition of technical competence

Figure 6

A **standard** defines properties – in the above example, these could be the dimensions and tolerances of the desk and its drawers. During manufacture of the desks, safety and worker protection regulations also have to be followed. Possibly, there might be regulations in force for the use of certain materials; thus, if the desks are made of wood, use of lumber from endangered species could be prohibited.

Metrology guarantees that measurements are exact and reliable so all parts will fit together as desired. Through **testing**, it is possible to analyze and prove properties and other characteristics such as the quality of the materials and of the finishes. On its part, **quality management** has two components: **certification** of conformity with the requirements of the applicable standards, in this case the desk components and the desks themselves, and **accreditation** – the formal recognition of the technical competence of the certifying body and testing or calibration laboratories. Thus, all parties involved in the manufacture of the desks, can be secure in the reliability of their counterparts.

Reliable quality services are necessary for the diversification of production and for a lasting creation of added value, as well as to ensure competitiveness and the rights of enterprises. This applies in particular to small and medium-sized companies, which have to rely on the support of services from a national quality infrastructure – QI.

The institutional form the QI will have and the range of services supplied within the individual components, must take into account the needs as well as the resources and limitations of the country [13].

The rules and guidelines help to ensure:

- safer, healthier, more environmentally sound products,
- improved quality and reliability,
- better operational compatibility between products,
- greater consistency in the delivery of services,
- easier access to and greater choice in goods and services,
- better product information,
- suitable products for vulnerable populations,
- lower costs and greater competition, hence lower prices for consumers. [17]

A national quality infrastructure is required to protect health, safety and environment when importing products and services that must comply with national verifiable requirements. Equity in commercial transactions is a result of working, under **equal conditions**, to give confidence to exporters of their compliance with the requirements of the destination markets, and other basic voluntary standards such as:

- Quality Management Systems (ISO 9001),
- Environmental Management Systems (ISO 14000),
- Food Safety Management Systems (ISO 22000),
- HACCP (Hazard Analysis and Critical Control Points),
- GMP (Good Manufacturing Practice). [3]

A QI is not a punitive system, rather it seeks to support technical competence and compliance with international requirements.

Such a national quality structure, comprised of **M**etrology, **S**tandardization, **T**esting and **Q**uality management with its components Certification and Accreditation, is widely known as a MSTQ Structure or similar abbreviations, or simply a QI (quality infrastructure), and represents a mainly voluntary system. Technical competence makes it reliable for every kind of application so that, instead of setting up costly parallel structures, industries, consumers, public sector and regulatory bodies can all benefit from it for quality and for consumer protection purposes. When properly implemented and recognized by governments, it reduces use of resources in each ministry to a “one-stop shop” and serves for any kind of product and service.

Although requirements for automotive parts, agricultural products, or health care are different, the general QI structure applies to all of them and can, once installed and internationally recognized, easily be extended to other products/services or adjusted to new requirements [28].

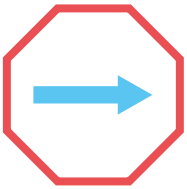
The system is designed to be mainly voluntary and follows technical requirements which can and should be used by regulatory bodies for compulsory application thus avoiding duplications.

Technical Regulations and Legal Metrology, are compulsory by definition; nevertheless, compulsory components should also refer to their voluntary counterparts and use their existing technical infrastructure.

Voluntary

- Standards
- Industrial metrology
- Accreditation

Mandatory



- Technical regulations
- Legal metrology

Figure 7

A well-structured and coordinated QI, with the transversal and interdisciplinary character of its components, needs strong support and acceptance from all benefiting sectors in order to be developed properly and to meet the various expectations within the quality assurance systems of relevant fields, such as all types of industries, health, environment, food processing, safety aspects, etc. Otherwise QI components become vulnerable to being developed and used as isolated solutions for a specific sector. Ministries or strong industrial sectors tend to set up QI components such as laboratories or standards activities for their own clientele, not considering that they are employing huge resources to set up parallel systems, which serve exactly the same objectives. Taking into account that a QI structure with all components will need extensive financial and human resources and, according to experience, between five and ten years until it becomes accepted through multilateral recognition agreements, efforts should be concentrated on implementing a single national structure [28].

National Quality Infrastructure (QI)
Quality systems in enterprises, testing and calibration laboratories require a national infrastructure capable of:

- ensuring access to traceable calibrations (for instance, through a National Metrology Institute),
- ensuring internationally recognized accreditations (for instance, through a national accreditation body),
- compliance with international requirements (ISO standards, CODEX),
- traceability of its national measurement standards,
- participation in international intercomparisons,
- mutual recognition with other countries.

3.1. Components of a QI

Detailed descriptions of each QI component follow in the next sections. It should become obvious that these components are closely interrelated and cannot be reliably implemented without all of them being actively working, integrated and internationally recognized.

> Standards provide a reference framework or a common technical language between suppliers and their customers – that facilitates trade and the transfer of technology [21].

In this sense, standards serve, for example, to describe the state of the art, point technical developments in the right direction at an early stage, define the requirements to be met by products and procedures, facilitate the interchangeability of technical components and set technical specifications for product testing. This gives market participants a uniform basis for assessing product quality and for goods to be labeled accordingly. Standardization promotes the rapid spread of technical knowledge and thus helps to make enterprises, particularly small and medium-sized, more competitive and innovative [13].

Standards do not stifle innovation or competition. Rather, they are the foundation for both. The standardized electrical plug and socket have not prevented anyone from producing new, interesting and innovative appliances. Instead, they have meant that anyone (in one or several countries) can buy a new gadget, safe in the knowledge they'll be able to power it [11].

Have you ever stopped to wonder why it is you can use your bank card almost anywhere in the world?

This and many other examples of convenience for consumers in everyday life are the result of international standardization by the International Organization for Standardization, ISO, and its partners [17].

As a part of the mandatory technical regulations, standards are an integral component of the economic and legislative system and a basic element in such important areas as environmental protection and health and safety at work.

The main tasks of a standardization organization are the support of the standardization process, harmonization and coordination (e. g. with current working standards). There are often systems in place, run by the private sector, thus ensuring a strong involvement of industry and other interest groups. Standardization organizations can also be public institutions [13].

The increasing globalization of trade and the emergence of new knowledge-based industries will increasingly depend on highly precise measurements to support their growth [19].

Measures are not a natural phenomenon. They have to be defined, described and made known; this is not new as figure 8 shows. Nowadays, these are the tasks of a national metrology institute. Measures are disseminated to users on a voluntary basis via a network of calibration laboratories, which have normally undergone a process of accreditation as proof of their competence. In the field of legal metrology, this task is also performed by the verification service that checks measuring instruments subject to legal control for compliance with the regulations, provides identifications, and punishes infringements [13].

Traceable measurements in Ancient Egypt

Unit of length standard:	the length of the Pharaoh's forearm and his extended palm
Materialized as:	the cube
Primary standard:	a granite cube, called "authentic master cube"
Working standards:	wooden cubes
Comparability:	recalibration of the wooden cubes each full moon
Calibration/traceability:	severe penalties in case of no fulfillment

The uniformity of the length measurements in Ancient Egypt reached an accuracy of 0.05 % over a distance of 230 meters.

Figure 8

Testing is perhaps the most common form of conformity assessment. It can include other activities like measurement and calibration. Testing also provides the basis for other forms – for example, it is the main technique used in product certification [16].

Protective provisions and standards are meaningless unless testing is carried out to ensure that they are being complied with. The tests are as varied as the areas that must be regulated. They can range from a simple visual check to testing under special laboratory conditions. If the test is passed, a special inspection stamp is often issued, such as a test badge for cars, or a verification mark for measuring instruments [13].

The general requirements for laboratories or other organizations to be considered competent to carry out testing, calibration and sampling are specified in the joint International Standard ISO/IEC 17025 [16].

The aim of quality management is to prevent mistakes and to guarantee and improve the quality of products and processes.

Proof that a quality management system is in place is normally issued through a certification procedure. Increasingly, such proof is being demanded before contracts are signed. Usually, the standard ISO 9001 is taken as a basis; it is the most widely internationally used system standard for quality management systems [13].

A business successful in its home market decides to compete in a number of export markets. The problem is that the business is unknown in these markets so it first needs to create confidence among potential customers that it can meet their quality requirements. To do so, the business aligns its processes with the internationally recognized quality management system standard, ISO 9001. It then has the system assessed by an independent, specialized body which issues the business with an ISO 9001 certificate confirming conformity to the standard. In approaching potential customers, the business can use its ISO 9001 certification/registration to establish itself as a reliable organization in which they can have confidence [20].

One of the main difficulties that exporters face is costly multiple testing and/or certification of products. Non-transparent or discriminatory conformity assessment procedures can become effective protectionist tools, or technical barriers to trade.

Achieving transparent, reliable and efficient conformity assessment practices is therefore a key to facilitating trade in goods and services while ensuring balanced, regulated public protection and fair industrial competition [7].

Conformity assessment is based on systematic testing to examine whether a product or a process fulfils certain requirements as specified in standards or normative documents. There are also standards defining the requirements for the conformity assessment authorities. If the test has been carried out by an independent third party, a conformity **certification** is issued. This is different from the conformity **declaration** made by manufacturers or by the customer, for example as part of a supply agreement. Often, declarations or certification of conformity must be provided before a contract is concluded or before a product is brought to the market. For instance, the CE mark denotes that a product meets European Union (EU) standards and facilitates free trade within the EU of products bearing this certificate [13].

First-party assessment. This is the technical term used when conformity assessment to a standard, specification or regulation is carried out by the supplier organization itself. In other words, it is a self-assessment. This is known as a supplier‘s declaration of conformity.

Second-party assessment. This indicates that the conformity assessment is carried out by a customer of the supplier organization. For example, the supplier invites a potential customer to verify that the products which it is offering conform to relevant standards.

Third-party assessment. In this case, the conformity assessment is performed by a body that is independent of both supplier and customer organizations [16].

Examples of certification marks are the German originated GS product safety label and the VDE label for electrical and electronic equipment, components and cables that are issued once the certification procedure has been successfully completed, and that indicate that the manufacturing process and the products are regularly inspected [13].

The TBT Agreement promotes the recognition of others' conformity assessment results as a way of reducing barriers to trade. It emphasizes that confidence in the continued reliability of conformity assessment results is a prerequisite to recognition of assessments [7].

Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks [21]. It is thus the formal confirmation, based on international standards, by an independent third party, that a body is competent to perform certain tasks. Accreditation is a means of building confidence in the work and the findings of testing and calibration laboratories and of inspection and certification bodies (conformity testing bodies). It applies for a fixed period of time and includes monitoring measures. It facilitates the mutual recognition of certificates of conformity and promotes international trade [13].

Accreditation reduces risk for business and its customers by assuring them that accredited bodies are competent to carry out the work they undertake. Accreditation by an IAF MLA member assures users that the accredited body is independent and competent, and delivers its services in the most time and cost effective way [1].

Accreditation bodies are established in many countries, often by government or with the encouragement of government, with the primary purpose of ensuring that certification/registration bodies in the country are subject to supervision by an authoritative body. Accreditation reduces risk for government, business and customers by ensuring, through regular surveillance, that certification/registration bodies are both independent and competent [1].

Users of certification/registration are protected from poor services when they are satisfied that the certification/registration body they use is accredited by an accreditation body which is an IAF MLA member. Accreditation bodies visit certification/registration bodies regularly, and witness their staff conducting audits, to ensure that both the body and its staff remain competent to undertake operations. Accreditation bodies require the bodies they accredit to be free of conflicts of interest or undue influence from interests that may benefit from a certification decision [1].

3.2. Inter-relationships between QI components

It should be clear that all components of the QI are closely related.

A **standard**, using dimensions and tolerances, cannot be defined without reference to reliable **measurements**.

Measurements must in turn be internationally **standardized** to avoid costly equivalences.

A product must be submitted to **testing** in order to determine **conformity** with the requirements defined in standards or technical regulations.

International compatibility requires that **testing procedures** be **standardized**, and also relies on reliable **measurements**.

Accreditation, based on international **standards**, is the procedure by which the whole process becomes reliable and trustworthy, leading to international trade and competitiveness.

3.3. International integration

International cooperation is a vital tool to dismantle technical trade barriers. It was the increase in international trade of industrial products in the mid-19th century that led to the founding of the Convention of the Metre in 1875, whose aim was to develop and introduce a standardized international system of units of measurement. Today, its work focuses on ensuring that the national metrology institutes are carrying out correctly their work of measuring and calibrating; it does this by means of confidence-building measures, such as comparison measurements. This ensures that measures are internationally comparable and facilitates mutual recognition of measurements and calibration.

For pragmatic reasons, the large number of existing national public institutes means there is a need for close regional formalized cooperation, on which the Convention of the Metre relies. Regional metrology organizations – RMOs ensure the accuracy of measurements within the region and promote the regional use of national measurement and calibration capabilities [13].

There are currently several such RMOs: the Interamerican Metrology System (SIM), the European Collaboration in Measurement Standards (EURAMET), the Middle East-North African Cooperation in Metrology (MENAMET), the South African Development Community Cooperation in Metrology Traceability (SADCMET), the Euro-Asian Cooperation of National Metrological Institutes (COOMET), and the Asia-Pacific Metrology Program (APMP).

The need to agree on international standards led in the late 1940s to the founding of the International Electro-technical Commission (IEC) and the International Organization for Standardization (ISO). Although over 70 per cent of ISO member organizations come from developing countries, their role in international standardization efforts has so far been small [13].

Regional organizations of accreditation include: the European Cooperation for Accreditation (EA), the Inter-American Accreditation Cooperation (IAAC), Asia Pacific Accreditation Cooperation (APAC), the Southern African Development Community Cooperation in Accreditation (SADCA) [1].

International organizations of accreditation bodies, such as the International Accreditation Forum (IAF) and the International Laboratory Accreditation (ILAC) promote the foundation of relevant regional organizations, build trust in the competency of their members and thus facilitate international recognition of certificates.

At the European level, the European Organization for Quality promotes development of and information on quality management systems. It develops harmonized training programmes with internationally recognized qualifications in the field of quality, the environment, and health and safety in the work place.

Within the World Trade Organization (WTO), the committees relevant to quality infrastructure – those on Technical Barriers to Trade (TBT) and on Sanitary and Phytosanitary Measures (SPS) – offer a forum to discuss questions relating to technical cooperation in this field. They conduct analyses of needs and endeavor to boost the exchange of information and experience between member states. In order to overcome technical barriers to trade, the members of the World Trade Organization (WTO) are called upon to promote the establishment of the appropriate infrastructure in developing countries and to help them implement these agreements [13].

In the long run, what is desirable is the avoidance of multiple standards, regulations, tests and accreditations. Nowadays, there is much emphasis on the concept of what is called **“One-stop shop” to achieve worldwide acceptance.**

World-wide product acceptance
"One-stop shop" to achieve **world-wide** acceptance means:
one product > one **world-wide** technical regulation
one product > one **world-wide** written standard
one product > one **world-wide** accreditation
one product > one **world-wide** test or measurement

This ambitious aim requires a worldwide-accepted system that comprises all components of the "one-stop shop", and is carried out by recognized competent technical organizations operating worldwide. As long as every economy implements the same structure on the national level, acceptance should easily be obtained. The strictest rule for success is that the systems be impartial and free of external influences. Recognition is granted by regional or international organizations based on technical competence and evaluated by peer groups. Results cannot be politically negotiated [28].

3.4. Impact of a QI on value (productive or supply) chains

Whilst it is relatively easy to calculate the costs of establishing and operating a quality infrastructure, it is hard to quantify its benefits. A functioning national quality infrastructure helps increase competitiveness in manufacturing and service delivery. This, in turn, increases productivity, helps create jobs, encourages investment and can promote more careful use of natural resources. A national quality infrastructure also helps to bring about improvements in health care and a more equal distribution of national wealth [13].

Third-party assessment may be required in certain business sectors by government regulations. It may be specified by the customer, or the supplier organization may choose it as a way of differentiating its product or service from others on the market [16].

3.5. A National Quality Infrastructure as a tool for regulators

Regulators are there to ensure that technical regulations exist and are properly enforced, particularly in areas related to the well-being of the population such as health, safety and the environment. They are usually based at ministries, secretariats or other official entities.

It would be extremely difficult for each and all official bodies having to do with these aspects to have all the resources required. And this is not even necessary – a sound national quality infrastructure can fill their different needs.
Independently of the technical area, a standardization body is able to provide world-wide information on existing standards. In addition, regulatory bodies can use the standards as basis for technical regulations. They have to enforce them in their countries. These may pertain to health and safety requirements of agricultural products, of foods, of drugs and medical devices, to packaging and labeling, to safety measures and equipment, to acceptable levels of contaminants, to environment-friendly processes, etc., areas where enforcement will probably be variously assigned to, for example, the ministries of agriculture, of health, of labor, of environment.

Measurements, whether physical or chemical, must always be traceable to the national metrology institute measurement standards, so they can effectively be reliable by proper verification and by traceability to the internationally approved measurement standards. Put very simply, the result of proper traceability is that something weighting, let's say, one kilogram in a given city will also weigh one kilogram anywhere else under equivalent conditions. All national bodies with legal metrology functions have to rely on the national metrology structure to ensure this traceability.

Testing laboratories, properly accredited, can carry out analysis in their specialized fields, independently of the products to be analyzed and of the final purpose, be it process control, product testing or analysis, enforcement of technical regulations, or whatever.

The same bodies accredited to grant certification of conformity with standards for commercial purposes can also do the same for technical regulations as required by local laws.

It should be clear that both voluntary and mandatory actions use the same highway, even if their destinations are different. Being able to rely on this national quality infrastructure, frees enforcement bodies or regulators from duplicating costly facilities and personnel.

Conclusions

- Technical Regulations should be based on ISO standards and Codex Alimentarius recommendations. One National Standards Body elaborates national standards – Responsible ministries issue Technical Regulations and notify to the secretariat of the WTO Committee on TBT and in case of sanitary and phyto-sanitary measures to the secretariat of the WTO Committee on SPS.
- Physical and chemical measurements should be traceable to National Metrology Institute (National Reference Laboratories) under BIPM-MRA.
- Testing and analysis should be conducted by accredited laboratories.
- Certification Bodies for products and management systems should be accredited.
- National Accreditation Body should be internationally recognized for all required types of accreditations by ILAC and IAF-MLA.
- Regulatory Bodies should use the national QI infrastructure (with its components internationally recognized).

Part 4 – The Five Technical Components of the National Quality Infrastructure

Of the five technical components of the National Quality Infrastructure, three of them – Standardization, Metrology, and Accreditation – are somehow unique and they are already organized on a regional and international level to assure compatibility with other economies through mutual recognition agreements – MRAs – on a basis of international peer evaluations. Each economy is responsible for the development, according to international guidelines, of the national entities and their offer of the corresponding services. The other two components – Testing and Certification – must also be available to users of the National Quality Infrastructure and they are linked to the system by using the standards from the national standards body, having measurement results traceable to the national metrology institute, and having their technical competence demonstrated and evaluated through the national accreditation body.

The following sections will show for each component what are its tasks, what services users will expect (value chain approach), and how they should fit into the current international scheme. Each component is represented by one or several graphs. In all of these, the value or productive chains are on the left side column, with an indication that the system is valid for all products and processes. The right side column details the main international and/or regional system existing in each case. The center block shows the national components and, through arrows, how they act as links between the national value chains and international recognition. Mandatory actions are indicated by black arrows.

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4.1. Standardization

It should be kept in mind that the function of standards is to facilitate, not to compel.

In order to recognize the work of the standards body as a national task and to avoid confusion due to possible rival activities within a country or between ministries, a **National Standards Act** defines the creation and the tasks of a single National Standards Institute for all standards to be nationally implemented. This National Standards Institute can be a private or public entity as long as it is a legal entity and officially recognized by the government. On the international level the National Standards Institute represents the country in the international organizations such as ISO, Codex Alimentarius or regional standardization organizations such as COPANT (Comisión Panamericana de Normas Técnicas) in the Western Hemisphere [28].

4.1.1. Standards (voluntary environment)

As long as they intend to be widely recognized, all QI activities, including quality management systems, best practices, certification and accreditation, depend on consensus between all parties involved regarding the agreed parameters and their permissible tolerances. This ensures that all parts of a product, irrespective of source, fit together with the same measure of accuracy. The same applies to the procedures employed for the manufacture of defined products, the drafting of standard-practice specifications, etc. [28]

Standard
Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods with which compliance is not mandatory [31].

Standards, technical codes and directives are needed to make the reproducibility and comparability of measurements, test results and quality parameters independent of the performing organization. While these do constitute a voluntary agreement, they nonetheless form an obligatory basis for **M**, **T** and **Q** components when harmonization for mutual recognition purposes is compelling. In addition to political intent, their implementation requires a private or public institution (National Standards Institute or formerly National Bureau of Standards) with the personnel and resources necessary to comply with their worldwide identical defined tasks: identifying areas of importance, bringing together interested groups (formation and management of standardization committees), adopting the elaborated drafts (approval), implementing them as national standards (information office, library of standards, publishing office).

As the procedures for the elaboration of every type of standard are the same and should follow international guidelines, only one National Standards Institute per country is necessary and economically justified to avoid duplication of efforts. The technical competence has to come from the different standardization committees comprising experts in the respective fields, e.g. for industrial standards, food standards, health standards or environmental standards. This structure guarantees that all national standards are developed according to the same procedure but with the respective expertise, and that they are registered in one national system or database. Any national or international user can thus find the entire and updated information in one location [28].

Standards can be cost reducing. As an example, a standard for interior doors has been set up by the productive sector, so that the building industry and the final users do not need custom-made doors and all interior doors produced locally can be interchangeable. If the Government puts out bids to build a group of schools, instead of going into detailed specifications for doors, bid conditions can specify that interior doors to be used follow that industry standard, thus reducing manufacturing costs and delivery delays. The same could be said for water and drain piping, electrical systems, materials for roofing and floors, etc.

Standardizing bodies should comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards, also known as the “Standards Code”, given as annex 4 of the WTO Agreement on Technical Barriers to Trade [31].

Standards and technical regulations

Figure 9

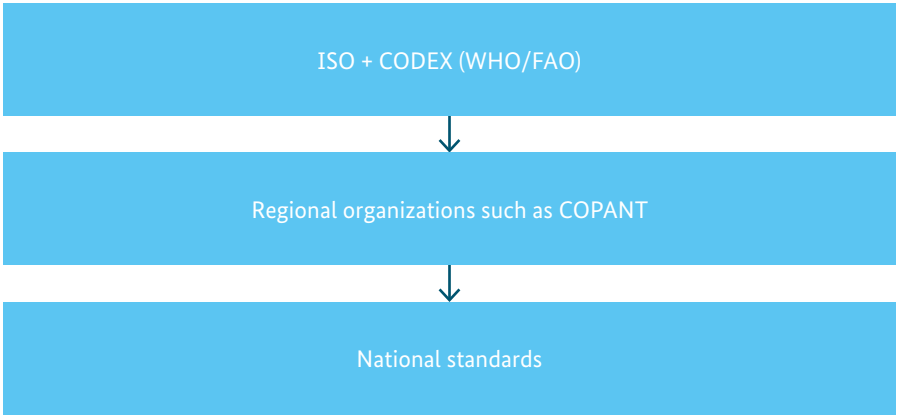
Without a functional system of standardization, particularly with respect to metrological, testing and quality standards in all fields of national interest, the **M**, **T** and **Q** scopes could perhaps be established as ends unto themselves, but not as providers of industry-oriented or customer protection oriented services [28].

On the other hand, in many industries international commerce would be impossible if countries adopt different standards. For example telecommunications, information processing, banking and financial services could not operate across national boundaries if they did not all obey the same rules [1].

The format of the credit cards, phone cards, and "smart" cards that have become commonplace, is derived from an ISO International Standard. Adhering to the standard, which defines such features as an optimal thickness (0.76 mm), means that the cards can be used worldwide [1].

Nowadays, standards will not be newly "developed" in each country but mainly adopted from international standards, e. g. ISO standards. In this case the standards are already accepted worldwide and have only to be adopted within the national system. Further harmonization processes are unnecessary [28].

Standardization is based on adoption



In some cases of only local interest, really new standards have to be drawn up; this might be standards for llama meat in the Andean countries of South America. Sometimes local adjustments may be necessary if a country does not have the technical or structural conditions to implement the international standard.

A similar situation can be found in specific sectors where the international recommendations do not come from ISO. In the food sector, for instance, standardized recommendations are elaborated by Codex Alimentarius committees [28].

The Codex Alimentarius Commission was created in 1963 by the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO), to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of this Program are to protect the health of the consumers and to ensure fair trade practices in the food trade, and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations [28].

4.1.2. Technical regulations (mandatory environment)

In some fields related to safety, health, environment and consumer-protection issues, directives have to be compulsory. As the term **standard** is used exclusively for voluntary application, a different term is internationally used for compulsory implementation: **Technical regulations**. Development and enforcement of compulsory technical regulations are a sovereign task of a nation, and thus governmental bodies – in general ministries – are responsible for their respective field of authority. Again, to avoid duplication of efforts, technical regulations should make reference to pertinent national standards as much as possible. If there are no national standards for the field to be regulated, the regulatory body could encourage the National Standards Institute to develop a standard in this particular field which will then be referred to by the respective ministry when issuing a technical regulation. This means that part of a voluntary standard, or the standard itself, may become a technical regulation As competent representatives of the ministries normally work actively in standardization committees, they will already have in mind which parts of the newly developed standards should be adopted in the future as technical regulations under their ministry [28].

The difference between a standard and a technical regulation can be seen in the following example. There are standards for bottles and standards for bottle closures; a mineral water bottler can buy each of these from a different supplier and be sure they will fit. On the other hand, in order to protect consumers, the Health Ministry may want to make sure there are no contaminants in the mineral water being sold; it will issue a technical regulation stating what materials can be used in the manufacture of bottles and their closures, and what concentrations of which elements are the only ones acceptable in mineral water.

Technical regulation
Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method [31].

With this concept, the voluntary standards and compulsory technical regulations are clearly separated and delegated to the entities responsible, although contradictory or multiple actions are ruled out [28].

Standards and technical regulations

Figure 10

Under the WTO agreement it is also the obligation of a signatory country to establish a **National Notification Authority** (NNA); this has to be a single government authority, responsible for the implementation of notification procedures, and to notify approved technical regulations to the TBT or SPS Secretariat at WTO in Geneva.

Additionally, an **Enquiry Point** has to be established, that is responsible for the provision of answers and documentation to all reasonable questions from interested members [28, 31].

Standards and technical regulations

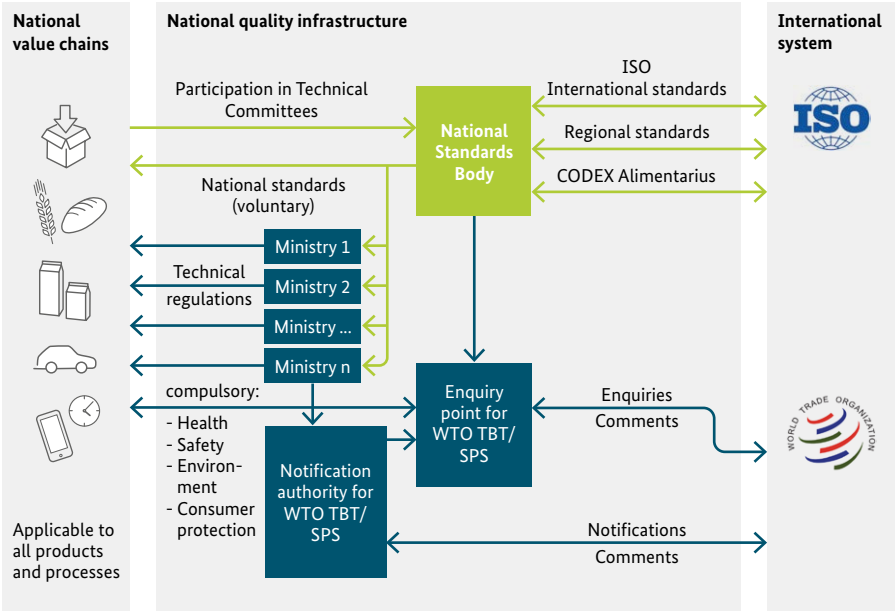


Figure 11

4.1.3. Additional buyer's standards (voluntary environment)

Specific clients or markets can mean compliance with additional standards. These standards may be different and/or additional to national standards or technical regulations.

For instance, a buyer of wooden desks may require a given type of finish; a buyer of furniture a certain range of specified colors for upholstery; a buyer of canned food a particular type of tomato sauce, etc. These would answer what is perceived as customer requirements in the particular market the buyer has in mind.

Companies can also set up their own requirements. Motorcar companies buying motor parts from a supplier will possibly want to specify types of materials, resistance to corrosion, strength, etc.

Retailers are becoming a market force to be reckoned with. As an example, many European retailers require additional food standards such as EurepGAP (Euro Retailer Produce Working Group – Good Agricultural Practice) for agricultural produce such as fruits, vegetables, salad greens, cut flowers, etc.

There are currently other standards required by certain groups such as eco or environmental standards, codes of good conduct, of social commitments, etc.

4.2. Metrology, calibration and legal metrology

The role of metrology is easily seen in the following:

- No **quality** without **quality control**,
- no **quality control** without **measurements**,
- no **measurements** without **calibration**,
- no **calibration** without **accredited laboratories**,
- no **accredited laboratories** without **traceability**,
- no **traceability** without **measurement standards**,
- no **measurement standards** without **metrology**.

4.2.1. Metrology structure

Put simply, metrology is the science of correct and reliable measurements. For some purposes, a distinction is made between scientific metrology (development of primary measurement standards or primary methods), industrial metrology (proper maintenance and control of industrial measurement equipment including calibration of instruments and working measurement standards), and legal metrology (verification of instruments used in commercial transactions, according to criteria defined in technical regulations).

Measurements are part of our daily life and their results affect decisions in many disciplines. Apart from consumer protection purposes in legal transactions (see legal metrology below), precise measurements in quality-related aspects are becoming increasingly important in globalized production with global working firms and worldwide local suppliers. But system and units must be defined before talking about measurements! The need to harmonize and to set up worldwide equivalent systems became obvious, not only in technical matters but also as a political framework. This harmonization started in Paris in 1875 with the Convention of the Metre.

The Convention of the Metre is a diplomatic treaty which gives authority to the General Conference on Weights and Measures (*Conférence Générale des Poids et Mesures*, CGPM), the International Committee for Weights and Measures (*Comité International des Poids et Mesures*, CIPM) and the International Bureau of Weights and Measures (*Bureau International des Poids et Mesures*, BIPM) to act in matters of world metrology, particularly concerning the demand for measurement standards of ever increasing accuracy, range and diversity, and the need to demonstrate equivalence among national measurement standards.

Representatives of seventeen nations signed the Convention in Paris, in 1875. As well as founding the BIPM and laying down the way in which the activities of the BIPM should be financed and managed, the Metre Convention established a permanent organizational structure for member governments to act in common accord on all matters relating to units of measurement.

The 11th General Conference on Weights and Measures in 1960 adopted the name *Système International d'Unités* (International System of Units, international abbreviation SI), for the recommended practical system of units of measurement [28].

The 11th CGPM laid down rules for the prefixes, the derived units, and other matters. The base units are a choice of seven well-defined units, which by convention are regarded as dimensionally independent: the metre, the kilogram, the second, the ampere, the kelvin, the mole, and the candela. Derived units are those formed by combining base units according to the algebraic relations linking the corresponding quantities [28, 29].

Apart from the internationally operating CIPM the continents have set up Regional Metrology Organizations (RMO), to compare and harmonize their metrological systems. The relevant RMO for the Asian countries is called Asia Pacific Metrology Program (APMP), in Latin America it is the SIM – *Sistema Interamericano de Metrología*.

In order to ensure that dimensions of supplied automotive parts or threshold values of contaminants in food products meet the requirements exactly, measurements have to be as accurate as necessary for the purpose. Additionally, it has to be borne in mind that every measurement has an “uncertainty”, as do test results and analytical research, due to statistical, human, or technical deviations [28].

How to guarantee that a kilogram, a meter, a second or fractions and multiples of the same are measured with identical results, independently of operator, location, environmental conditions and characteristics of the measuring instruments?

How to assure that 1 kg in laboratory A in Argentina weighs exactly the same as 1 kg in laboratory B in Germany ?

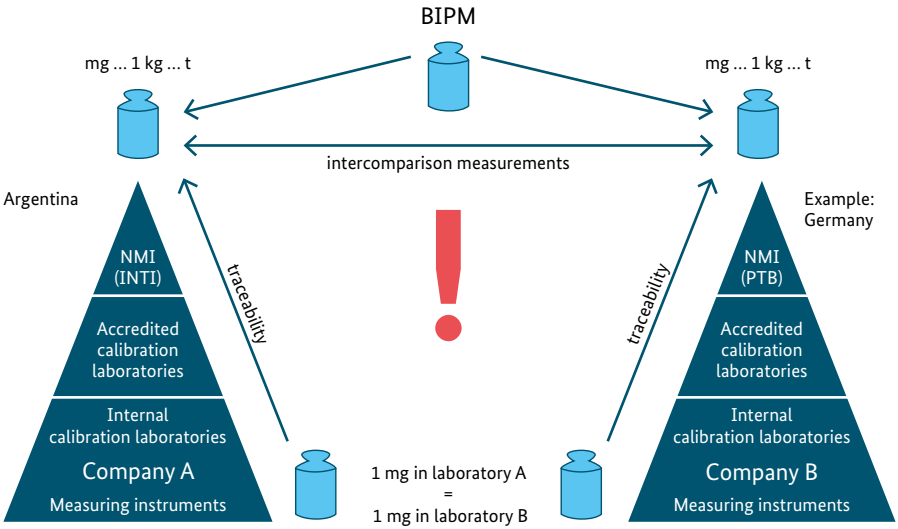


Figure 12

Only by a clearly defined structure and measurement hierarchy applied in every country of the world, harmonized through regional organizations, and finally coordinated by the BIPM as a worldwide metrological system, with accepted mutual recognition of measurement results performed by the members.

Metrological infrastructures – Physical definition of standards

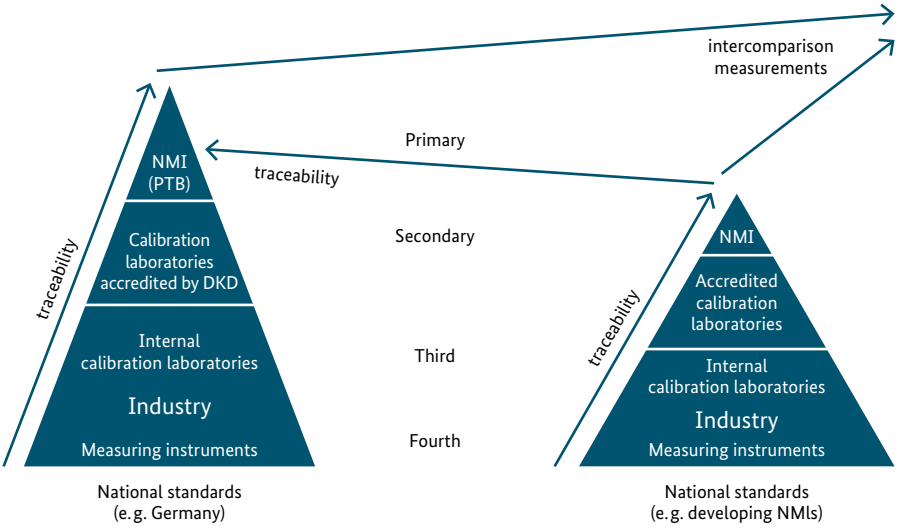


Figure 13

Primary measurement standards are those that are a materialized measure, measurement instrument or system, or reference material, that defines or materializes a given measurement unit, and as such they do not themselves require traceability. The other levels (second, third, and fourth in fig. 13) require traceability to a primary standard, with a descending order of uncertainties of measurement. Maintenance of some of the primary measurement standards requires quite stringent conditions. Metrology institutes in countries with little demand or relatively low uncertainty requirements do not necessarily have primary standards as their national measurement standards, as long as theirs are traceable to an internationally recognized NMI with primary standards. They must guarantee reliable traceability, and intercomparison measurements will vouch for their technical competence.

In the above example, the national measurement standards of a developing NMI in a given country are traceable to the German national metrology institute PTB, which demonstrates competence through participation in worldwide intercomparison measurements. The country with the developing NMI demonstrates its competence by participating in international and/or regional intercomparison measurements.

International Comparisons for the global MRA

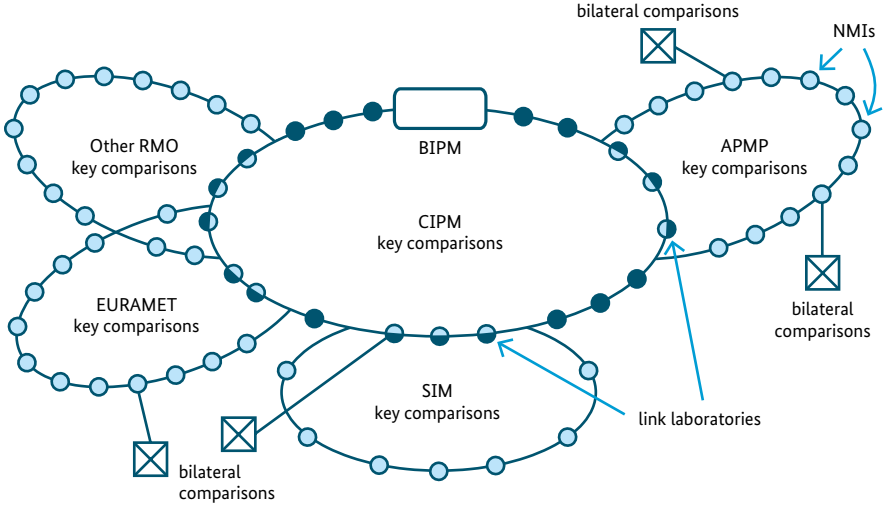


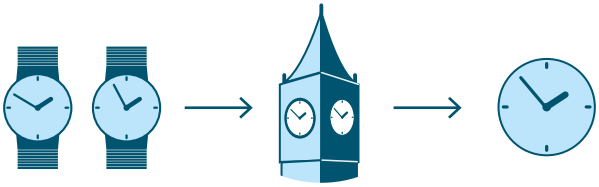
Figure 14 (Source: BIPM)

In this graph, NMIs are represented by circles. The light blue circles correspond to NMIs that participate in regional key comparisons. Dark blue circles correspond to NMIs participating in CIPM key comparisons (at the level of primary measurement standards). Circles half light and half dark blue represent those NMIs participating in both types of intercomparisons and thus being the links between CIPM and regional comparisons. Squares represent bilateral intercomparisons.

Assessments by peer groups and successful results of comparison measurements are prerequisites to be accepted by the club members. A key criterion is not the highest precision of measurement but the highest reliability of the declared measurement capabilities. These so-called **Calibration and Measurement Capabilities** (CMC) are listed in a database administered by the BIPM in Paris and published on the Internet. The database is frequently updated and extended; it shows the national measurement capabilities of each country for physical quantities and it has recently been extended to chemical quantities related to analytical capabilities e.g. for the determination of heavy metals, pesticides or antibiotics. These data play an important role in international trade when it comes to the level of contaminants in agricultural or food products where internationally recognized certificates are required. Therefore, free trade agreements are beginning to refer to these measurement capabilities.

The measurement needs of industry are defined by quality aspects of the products, manufacturing processes and clients' requirements, which are generally defined in written standards. International quality standards (ISO 9000, ISO/IEC 17025, etc) require **traceability** of measurements. The concept of traceability (not to be confused with the documentation traceability in food processing from "farm to fork", see part 6) means an uninterrupted chain of comparison measurements with increasingly higher accuracy instruments (smaller measurement uncertainty), starting at the instrument used in industry up to the national measurement standard. This regularly repeated measurement to compare a measuring instrument against a measurement standard with higher accuracy is called "calibration" [28].

Definition of Standard and Traceability
Most persons have a wristwatch which shows *approximately* the same time.
But is it *exactly* the same time on each watch? How to define the *master* time?



Should the Standard be valid on a local, national, regional or international level?
Which accuracy and uncertainty are necessary?

Figure 15

Traceable measurements

	Ancient Egypt	Modern world
Unit	cube	meter (SI system)
Primary or reference measurement standard	granite cube	gauge blocks/laser, interferometer
Working measurement standards	wooden cube	micrometers, vernier caliper, etc.
Application	manufacture of stone blocks or pieces	control of dimensions
Recalibration period	each full moon	according to frequency of usage
Traceability	local	international

Figure 16

4.2.2. National Metrology Institute

In general, every country has a National Metrology Institute – **NMI**, which is responsible for the development and maintenance of the national measurement standards in physical and chemical quantities. Irrespective of whether these standards physically have the highest achievable accuracy (primary standards), when they are declared as the national measurement standard of a nation, they represent the countries‘ capability. Calibration activities are also an essential part of the national metrology system and thus of the national quality system. As the **NMI** is indispensable and part of the national quality system, it must be mentioned in the structure of a National Quality Act. Additionally, its creation, function, tasks and institutional status should be defined in a National Metrology Act [28].

The National Metrology Institute – **NMI**, can be considered the national custodian and verifier of reference standards and as such it must obtain, conserve, develop and disseminate the basic measurement units and the highest level of calibration standards. It provides traceability to the national system and it ensures that international technical guidelines are followed for the metrological performance and testing procedures of measuring instruments subject to legal controls, and from the point of view of manufacturers it ensures that their products meet international specifications for metrological performance and testing.

Metrology and calibration

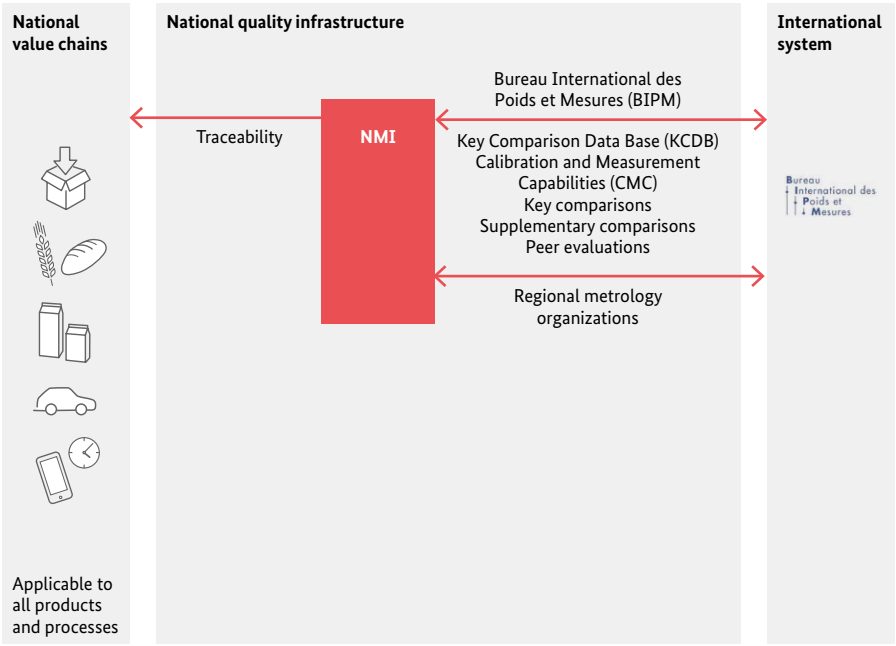


Figure 17

The National Metrology Institute main functions can be stated as follows:

- it is the primary metrology laboratory; as such it develops national measurement standards and disseminates their exactitude to industry and users in the country,
- it establishes and maintains the national measurements system, giving technical support to the network of secondary and tertiary laboratories,
- it provides traceability to the national system and through it to the international system,
- it offers technical support to industry in everything related to measurements, reference materials, calibrations and data to establish traceability of their measurements,
- it participates in modernization and technology transfer between academia, industry and government, contributing to reinforce the scientific and technical infrastructure required by industry to compete in the present global markets,
- it supports development of reference standards and the national system of standards,
- it facilitates international harmonization and compatibility of measurements,
- it represents the country in the regional metrology organization RMO and the worldwide metrology system coordinated by BIPM,
- it participates in internationally organized intercomparison measurements, and
- together with the national accreditation body it organizes national intercomparison measurements for calibration laboratories in the country.

Role of the National Metrology Institute (NMI) in economic and social development

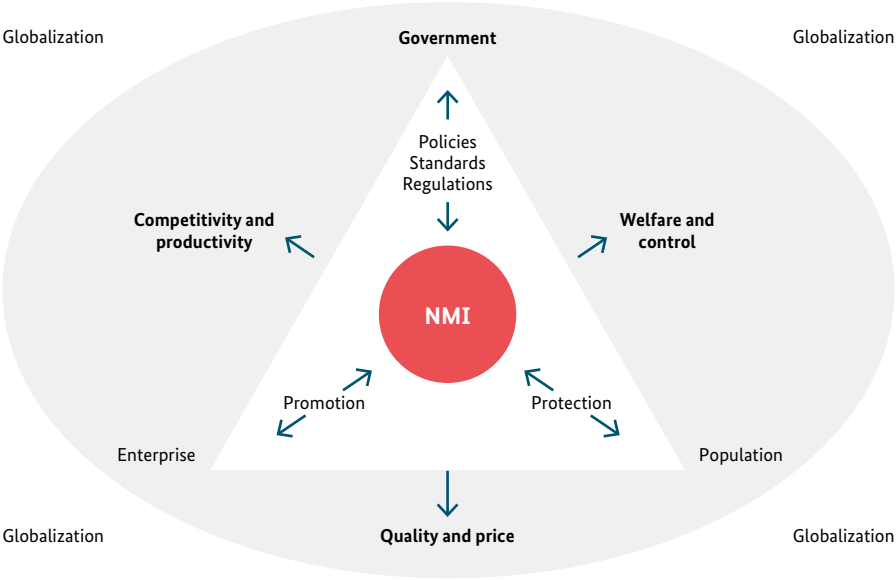


Figure 18

4.2.3. Calibration laboratories

It is important to note that defective calibrations can result in serious problems and even accidents, and that these must be avoided.

The task of a National Metrology Institute is to develop and disseminate measurement standards in the country, and calibration of measuring instruments. In small economies, with little demand for calibration, the NMI can cover almost every demand. This is not the case in industrialized nations. As an example, in Germany where many millions of measuring instruments in industry are traceable to PTB – the national metrology body – only those instrument of higher accuracy are calibrated there; other levels are handled by secondary and tertiary calibration laboratories. A number of secondary calibration laboratories all over the country are necessary to satisfy this demand in a customer-oriented manner [28].

Calibration laboratories can be private or public enterprises, using secondary or working measurement standards traceable to their NMI to calibrate customer instruments. The uninterrupted chain of traceability from an industrial measuring instrument to the National Measurement Standard remains guaranteed within given uncertainties [28].

Besides the traceability of the reference standards used for customer calibrations, a calibration laboratory has to implement a quality system according to ISO/IEC 17025 and to demonstrate its technical competence through an accreditation of the calibration scope offered to its clients.

Metrology and calibration

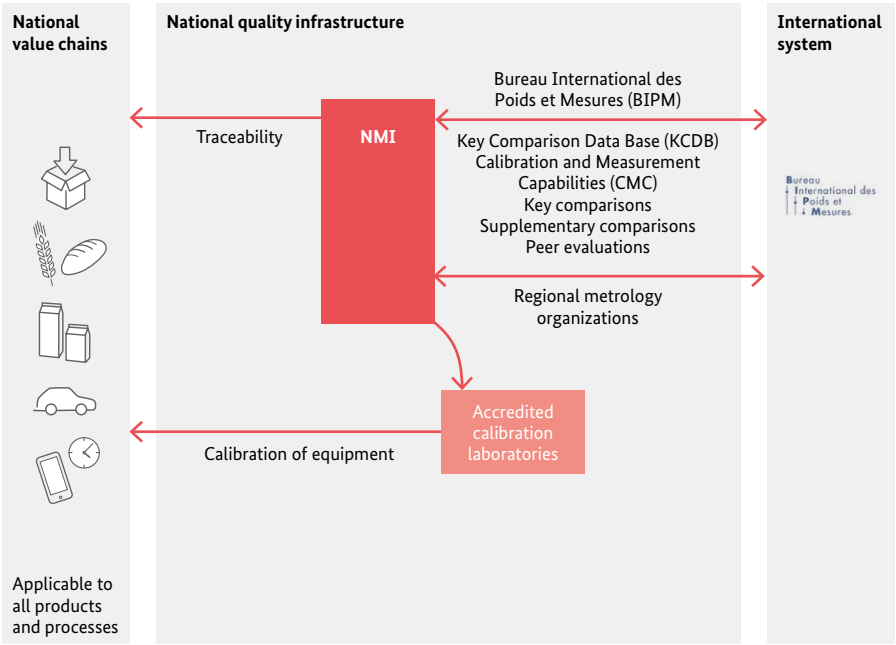


Figure 19

Calibration is based on traceability

SI units

National Metrology Institutes (NMIs)

Accredited Calibration Laboratories

Industry, consumers, regulators

– and –

Calibration is based on competence with

- Quality system in place
- Participation in proficiency testing and intercomparisons
- Accreditation according to ISO/IEC 17025

4.2.4. Metrology in Chemistry (MIC)

In former times metrological infrastructures were mainly related to physical measurands. With more emphasis on environment, health, food, and genetic manipulations, the reliability of chemical analysis is becoming increasingly important [28].

> Public concern in Europe about unanticipated adverse effects of the use of transgenic seeds and consumption of transgenic foods has led to demands for mandatory labeling of such seeds and foods and represent a major threat to Canadian exports of canola, wheat and potatoes (Canola alone represents over $2B in Canadian farm gate value). Since any such technical barrier to trade will be based on measurement of GMO (Genetically Modified Organisms) content in commodity foods or food products, accurate and equitable internationally accepted measurement standards will be of critical importance to the Canadian agricultural industry. In the future, market acceptance of any GMO product may be subject to internationally traceable measurement standards [19].

The simple hierarchical principle as it works in physical quantities cannot be applied in the chemical field, as there are thousands of known parameters which are not directly linkable to SI units. Other measurement standards with worldwide acceptance have to be defined. A system complementary to SI is being developed, which is based on “Certified Reference Materials” and “Primary Methods”. As in the case of physical quantities, the rest of the known environment such as inter-comparisons between **NMIs**, or declarations of Calibration and Measurement Capabilities (CMCs), the publication of results on the BIPM website, and regional or worldwide technical committees, is already functioning.

In some countries, besides the physical parameters, the **NMIs** try to also develop chemical measurement standards; this is the case in the USA – NIST, in Mexico – CENAM, and in Korea – KRISS.

Another option, especially for **NMIs** with none or little background in chemical measurements and the production of reference materials, is to set up a network of "Designates". In this case the **NMI**, as signatory to the BIPM-MRA, designates competent laboratories as National Reference Laboratories for specific fields of national interest. In the assigned field, these laboratories assume the functions of an **NMI**, including international representation of the country in, for instance CCQM (Consultative Committee for Amount of Substance), participation in international intercomparison measurements, and declaration of CMCs for their own country.

National Metrology in Chemistry System

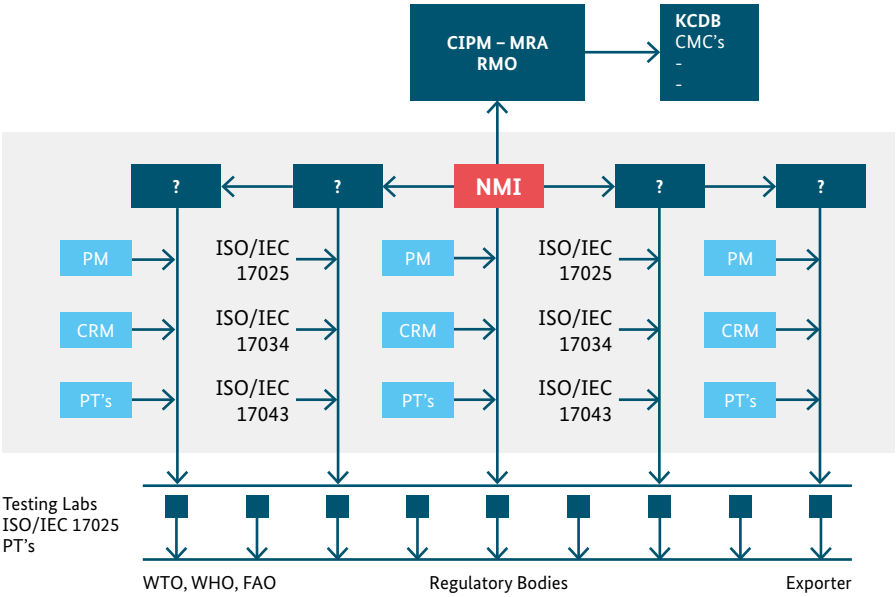


Figure 20

PM stands for Primary Methods (methods of higher order!), which could be considered primary measurement standards. CRM stands for Certified Reference Materials, the equivalent of reference measurement standards. PT's are the proficiency tests and they take the same place as intercomparisons.

Until recently, one example was Australia but finally the designated laboratory for MIC merged with the **NMI** to become the National Measurement Institute in Australia – NMIA, now covering all metrological aspects.

A well functioning national MIC system exists in Germany where the **NMI** has officially designated several other institutes for reference materials, clinical and environmental parameters.

Metrology in Chemistry in Germany

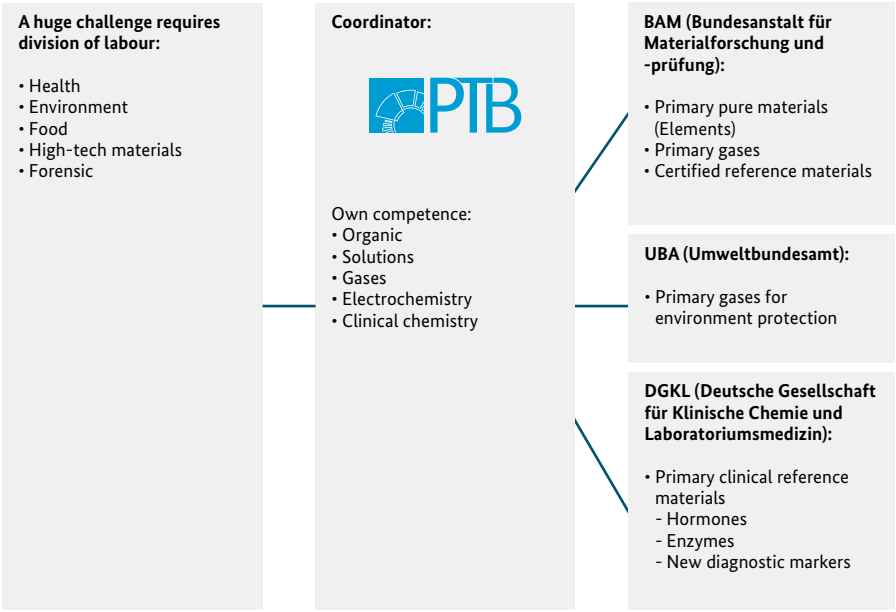


Figure 21

Main requirements for this process are:

- definition of designation criteria,
- designation of selection process,
- preparation of a legally binding contract,
- follow-up of implementation.

Partnership formation in Germany

Coordinator:

PTB

Own competence:
- Organic
- Solutions
- Gases
- Electrochemistry
- Clinical chemistry

Selection Process:

Knowing each other (competence)

↓

Intercomparisons

↓

Participation in international comparisons (EURAMET, CCQM)

↓

Accreditation of test laboratories

Partner institutes actually:

BAM, UBA, DGKL

Competence:
- Pure Materials
- Gas mixtures
- Gases for environmental protection
- Clinical reference materials

Figure 22

Once such a scheme is developed and implemented, and this can take several years, the system will function according to figure 20 or, as in the case of Germany, according to figure 23:

Network of Metrology in Chemistry in Germany

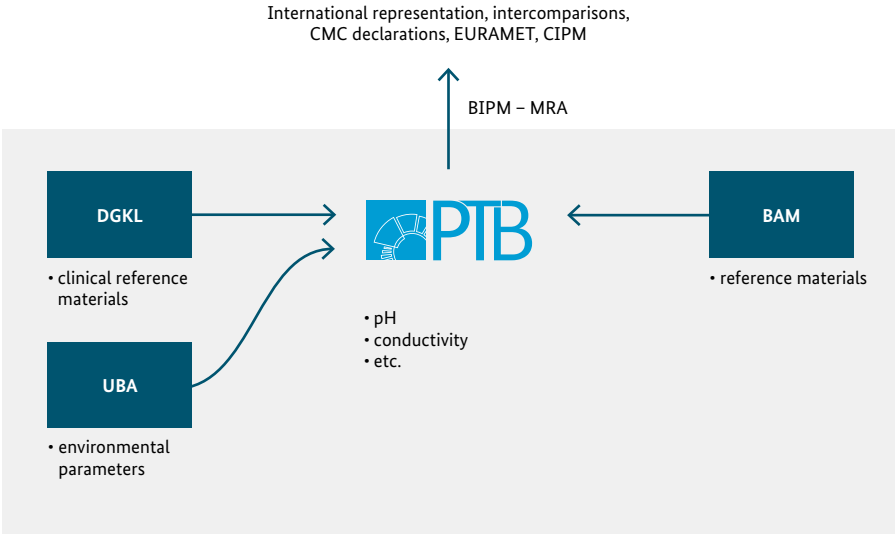


Figure 23

For developing **NMIs** particularly, networking in MIC represents a great opportunity to benefit from existing laboratory capabilities in the chemical parameters of interest (food safety, environment, minerals, fossil fuels, etc.) for export compliance or consumer protection purposes.

Thailand and Chile are countries presently developing a network type of system for metrology in chemistry. The difference lies in the fact that Thailand has a **NMI** for physical and a few chemical quantities and it wishes to expand national coverage through institutes designated for complementary fields. Chile does not have a centralized **NMI** but rather a network of laboratories acting as custodians of national measurement standards – LCPN – for physical quantities and expanded with national reference laboratories in chemical quantities with the purpose of establishing a "virtual **NMI**", equivalent to a classical **NMI**.

According to ISO/IEC 17025, the concept of measurement traceability must also be applied to chemical measurements. A system with calibration of instruments and National Measurement Standards is also necessary for chemical measurements [28].

The BIPM has a Consultative Committee for Amount of Substance (CCQM) with working groups for organic, inorganic, gas, surface analysis and bio-analysis. Annex 3 gives more details on the CCQM measurement categories for amount of substance.

There is no specific recipe for the development of MIC; national requirements can be very different but economies will normally emphasize the development of reliable and traceable measurement of chemical parameters requested by target markets for their main export products such as seafood, wine or vegetables.

National consumer protection purposes are mainly related to drinking water, food and pharmaceuticals. In contrast to the relatively few physical standards, there are thousands of chemical parameters and matrices to consider so that priority selection of measurements is indispensable.

Identification of needs (chemical parameters)

Evaluation of available capabilities (existing laboratories)

Analysis of the gap (demand-offer analysis)

Selection of the proper model e.g centralized NMI or NMI and designates

Attainment and maintenance of government support

Development of capabilities and dissemination of services

Metrology and calibration

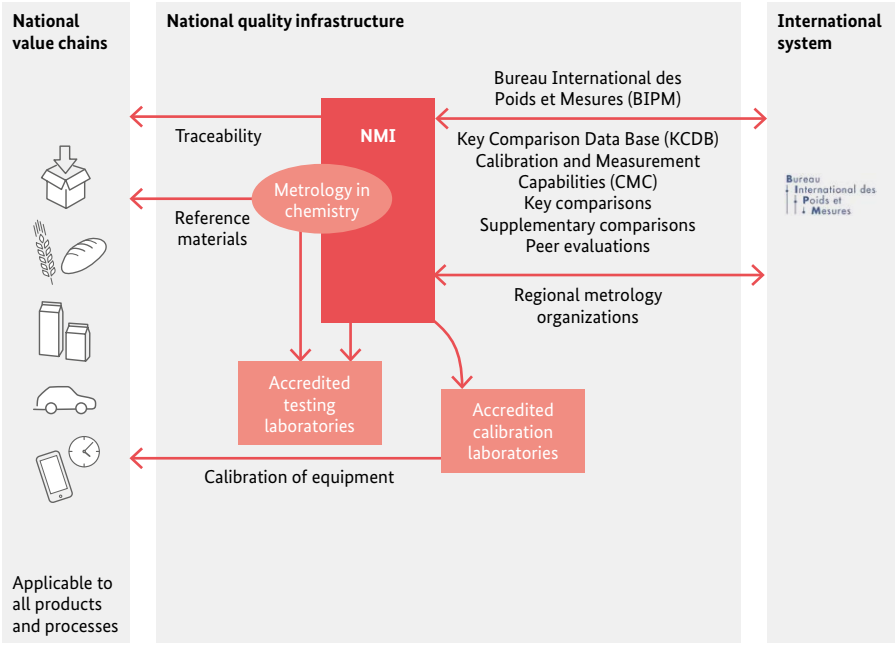


Figure 24

4.2.5. Legal Metrology

Customers who buy a kilogram of sugar, fill up tank at a gasoline station or just use a metered taxi, have to rely on the amounts shown when they pay for the product or service. They have no possibility of verifying on an individual basis all commercial transactions, and so they need to have a protector assuming this responsibility for the consumers. It is a sovereign task of a government to protect its citizens from unintended or fraudulent losses, and thus it is a legal matter to control correct measuring results related to commercial transactions and to impose and enforce fines [28].

In contrast to the described **calibration** of measuring instruments for quality aspects, what legal metrology officers do is to **verify** measuring instruments, that is, to check if the indicated value is within the acceptable tolerance defined in, for instance, a technical regulation [28].

Calibration (industrial metrology)
Regularly repeated measurement to compare a measuring instrument against a measurement standard with higher accuracy to obtain information about the necessary correction and measurement uncertainty to be considered for said measurement instrument.

Verification (legal metrology)
Verification that values given by measuring instrument are within the acceptable tolerances specified in a technical regulation (pass or no pass!).

Verification offices usually count on their own technical infrastructure, mainly mobile to be able to verify in-situ, but they trace their verification standards back to the same National Measurement Standards in the National Metrology Institute as does a calibration laboratory in industry [28].

The *Organisation Internationale de Métrologie Légale* (OIML), organizes the international harmonization where recommendations for standardized measurement and verification procedures are elaborated. In some continents, regional organizations are also established, such as the Asia-Pacific Legal Metrology Forum (APLMF) in Asia [28], and the Legal Metrology Working Group of the Interamerican Metrology System, SIM.

Metrology and calibration

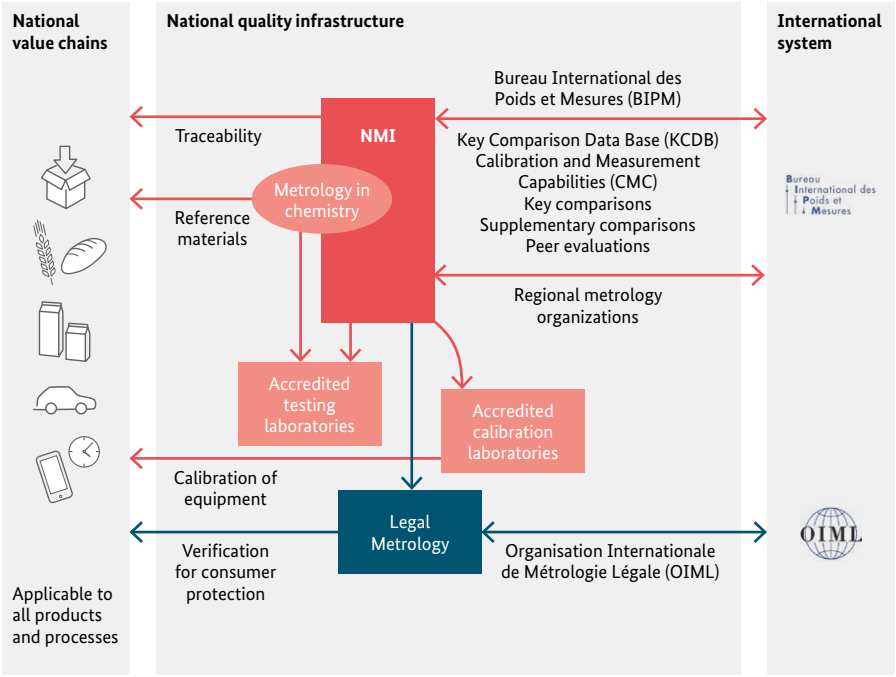


Figure 25

As in other fields, such as the Codex Alimentarius, these OIML recommendations can be adopted by the National Standards Institute as national standards. Later on, the ministry responsible for consumer protection or legal transactions, the Ministry of Commerce for instance, releases technical regulations by referring to these national standards [28].

Metrology is based on recognition

BIPM, CIPM-MRA, KCDB

Regional organizations, such as SIM and APMP

National metrology institutes (NMIs)

4.3. Testing

In all areas, testing serves as a means of studying the characteristics, contents and/or quality-determining parameters of products, components, substances, etc. Depending on the respective testing field (chemical, microbiological, physical testing, etc.), the methods of analysis, test and/or inspection will differ along with their respective analytical equipment and test apparatus. All tests of whatever type are decisively dependent on universally applicable, recognized guidelines defining how and under what circumstances the test in question is to be implemented. In this connection, standardization again assumes a major role, since many test methods are standardized in order to guarantee that the results obtained will be mutually comparable and reproducible [28].

The reliability of tests conducted depends, of course, on the correct operation and accuracy of test and measuring equipment, and the latter in turn depends on traceable calibration [28].

Results from testing and analysis can serve different purposes. If used as a routine test in the production process as part of the quality system, testing will normally be done by a small internal laboratory of the company, focusing on internal demand. In this case supplier and customer represent the same owner. No third party is involved, external evaluation is not required. The internal testing laboratory can perfectly be integrated into the ISO 9000 quality system of the company. Technical competence is a requirement within the company's quality policy, and traceability of measurements and tests are also required in ISO 9000 [28].

It would be extremely costly for every single producer, consumer group or government agency in a country to set up laboratories for all the testing required. It is thus advantageous to make use of existing specialized laboratories and to set up only those that are not yet available. These laboratories can either be private or they can function at government agencies; what matters is that proper accreditation makes them available and reliable for different purposes. Commercial testing laboratories offer their capabilities to any client seeking this service. In this case the client will trust the testing results only if the laboratory can show, without doubt, its technical competence. As the customer normally has no means of evaluation, the solution is a third party assessment according to defined criteria by a competent and recognized body.

Testing System

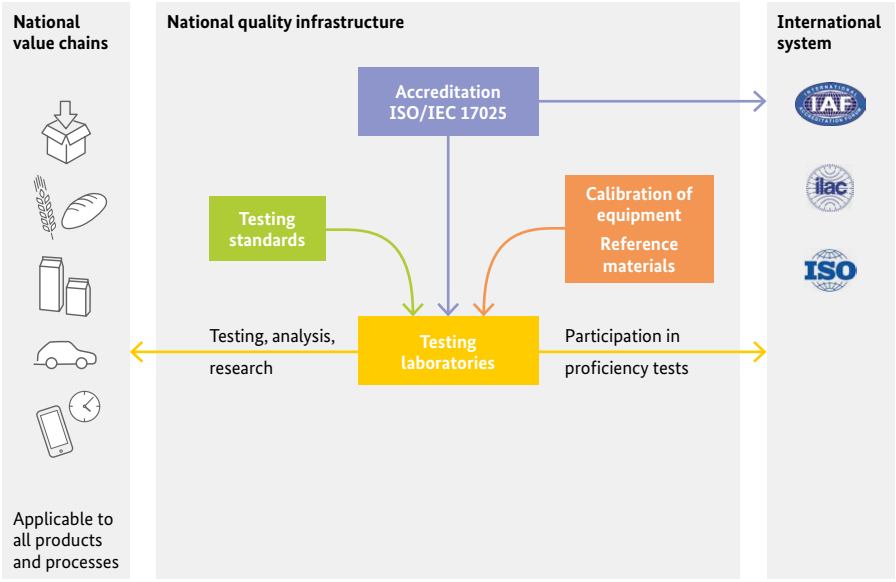


Figure 26

This type of system is harmonized and established worldwide. The quality management and technical competence criteria are defined in the international standard ISO/IEC 17025, which applies exactly the same criteria to all kinds of testing and calibration laboratories. There is only one exception, that for clinical and medical laboratories where the derived standard ISO 15189 is applied to better meet the requirements of this field. An accreditation body will perform assessment and surveillance [28].

Reliable and recognized national laboratory infrastructure

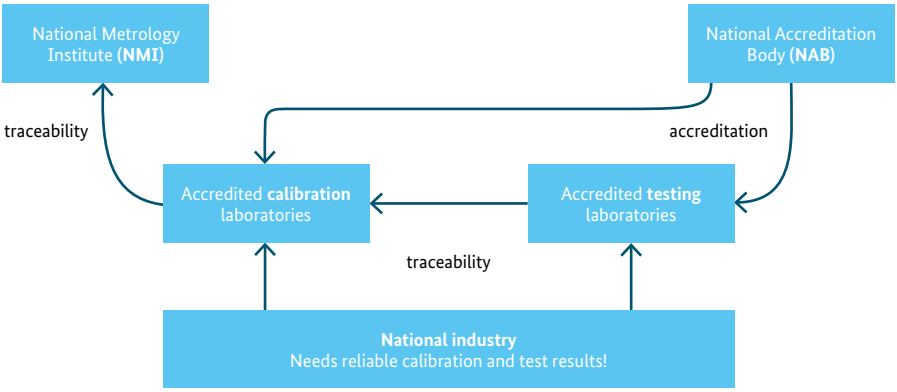


Figure 27

The public or private sector can set up testing laboratories according to the needs in a country. No preferences or exclusions should be implemented but accreditation, as competence criteria for customers, must be demanded irrespectively of whether it is a governmental or non-governmental laboratory.

When an equivalent sample is tested in, say, five different testing laboratories and gives five different results, there is a waste of resources and this incoherence in the results leads to a justified lack of confidence. That is one of the reasons why testing laboratories should be submitted to an accreditation process.

Testing is also a means to determine and to ensure compliance in the application of technical regulations.

Test reports can be used for voluntary or compulsory purposes, as long as the conditions set by the regulatory body, and which are defined in technical regulations, are fulfilled. To avoid double testing structures, regulatory bodies should make use of a laboratory, whether public or private, as long as it is accredited by an internationally recognized body. The key criterion “technical competence according to international standards” can and should also be recognized by regulatory bodies [28].

Testing is based on proven technical competence

ILAC-MLA

↓

National Accreditation Body

↓

Evaluation, proficiency testing, intercomparisons

↓

Testing

To summarize: without the standardization and metrology components and without accreditation, no reliable, internationally recognized testing component can emerge within the scope of quality policy.

4.4. Certification

Through assessments, certification confirms conformity with requirements defined in written standards. Recognition can be achieved by using standards and assessment procedures which are implemented worldwide (ISO-Standards, Codex Alimentarius recommendations, etc.). Similar to the situation described for testing and calibration laboratories, a third party assessment of the competence of the certification body and regular surveillance visits by an accreditation body will confirm reliability and facilitate international recognition [28].

Conformity assessment
Checking that products, materials, services, systems or people, measure up to the specifications of a relevant standard or technical regulation [25].

Different kinds of certifications are known:

4.4.1. Certification of management systems

Management systems demonstrate that the enterprise in question has implemented procedures to structure and document its administration and management processes. It does not automatically lead to a good and competitive product or service but, due to clearly defined internal structures independent of the personality of the employees, it does avoid a lot of possible errors. The documentation of all processes facilitates the detection and tracing of errors in order to take corrective actions [28].

Some worldwide-accepted management systems which can be certified by certification bodies are:

- Quality management systems according to the ISO 9000 series
- Environmental management systems according to the ISO 14000 series
- Occupational health and safety systems according to the OHSAS 18000 series
- Hygienic systems: Hazard Analysis and Critical Control Point (HACCP)
- Good practices (Good Manufacturing Practice, GMP) etc.

Although some certifications are according to ISO standards and others according to FAO/WHO Codex Alimentarius standards, the same certification body can certify both types.

Harmonization processes between ISO and Codex Alimentarius have already led to the ISO 22000, a combination of ISO 9000 and HACCP, specifying requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption [28].

4.4.2. Certification of products

Product certification proves that production processes, contents, properties, etc. of a product comply with the requirements of a written standard. This type of certification is mainly demanded for products where security aspects, health care or food safety, play an important role.

Product certificates with their respective marks exist in most countries of the world. Many of those have only national acceptance if issued by a national certification body that does not have an internationally recognized accreditation.

Some examples of product certifications related to general safety aspects which also have international relevance are [28]:

- CE: European Union compliance mark
- VDE: Electrical equipment quality mark
- GS: Safety certification

Examples of specific food aspects are [28]:

- Organic or bio product certification
- GMO (Genetically Modified Organisms)
- Halal (muslim food requirements)
- Kosher (jewish food requirements)
- EurepGAP

By making a self-declaration of conformity, a supplier organization avoids the costs of third-party assessment. A supplier may decide to take this option if it believes that it enjoys a sufficiently high market reputation for it to dispense with independent confirmation of conformity. However, supplier's declarations may not be appropriate in all cases, particularly where the health, safety or environmental risks of the product concerned are higher. A self-declaration does not exempt the supplier from its responsibility to meet relevant regulations – for example, in relation to product liability – and such declarations generally need to be accompanied by effective post-market surveillance [16].

A wide field of product certification is related to food safety. In this case certain properties of food commodities, or levels of contaminants or residues are certified, mostly according to Codex standards or technical regulations of importing countries. Compliance exists when test results from analytical laboratories confirm conformity.

Certifying bodies for food safety related issues are in many countries under governmental departments or ministries, which are authorized by law but have not necessarily proven their technical competence. A reliable certification system should, on the other hand, not depend on nationally delegated tasks but on demonstrated technical competence, accredited by an internationally recognized accreditation body. As long as this is not the case, frequent and costly inspections by importing countries is the only alternative [28].

Clearly, product certifiers depend heavily on a reliable **S**, **M** and **T** structure. If the test results from the subcontracted laboratory cannot be trusted, there is no basis for a reliable product certificate [28].

The only way to achieve international recognition for the certification certificates is through accreditation of the certifier by an internationally recognized accreditation body.

Certification system

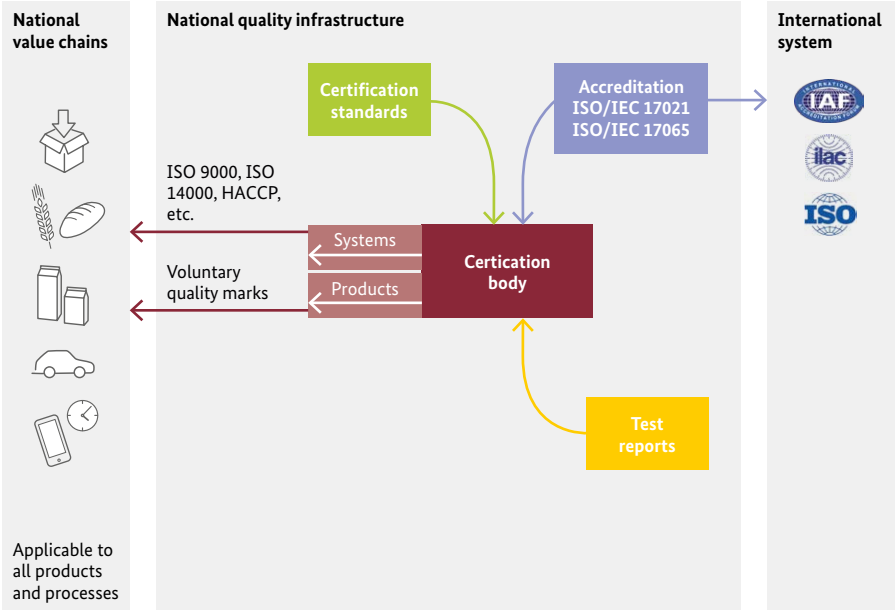


Figure 28

For mandatory certification required by a regulator, the same (private or public) certification body can be used because the process is exactly the same except that a mandatory technical regulation is used as the basis instead of a voluntary standard. Technical competence is assured through the accreditation.

Certification system

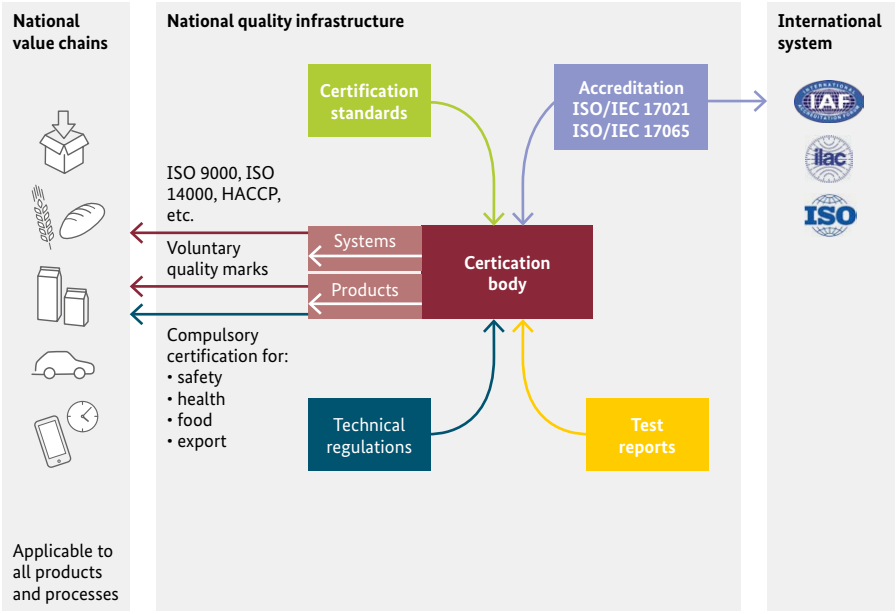


Figure 29

Certification
Voluntary, such as a quality mark, to promote products and give a market advantage

Mandatory, compliance with technical regulations, as in fire extinguishers or medicaments.

We have already mentioned that assessment of conformity with requirements as defined in written standards is the field of certification, and that both management systems and products may be certified.

Harmonizing conformity assessment procedures around the world also has far-reaching benefits for international trade in general. Agreements among nations or regions on the mutual acceptability of requirements, assessment methods, inspection or test results, etc., can all help to reduce or remove so-called technical barriers to trade.

IAF-MLA accreditation

Certification body

CASCO ISO/IEC Guides

Standards, technical regulations, laboratory reports

Certification

ISO has a specific committee, CASCO (Conformity Assessment Committee), whose work is centered on the areas covered by the ISO/IEC Guides:

- Vocabulary and general principles of conformity assessment
- The development of technical specifications suitable for use in conformity assessment
- Code of good practice for conformity assessment
- Operation of testing and calibration laboratories
- Proficiency testing by interlaboratory comparisons
- Inspection bodies and activities
- Supplier‘s declaration of conformity (SDoC)
- Product certification bodies and activities
- Management system audit and certification bodies and activities
- Personnel certification bodies and activities
- Marks of conformity
- Accreditation
- Peer assessment
- Mutual recognition of conformity assessment results. [17]

To facilitate trade at the international, regional, national and sub-national level, ISO/IEC Guide 60:2004 (Conformity assessment – code of good practice) recommends good practices for all elements of conformity assessment, including normative documents, bodies, systems, schemes and results. It is intended for use by individuals and bodies who wish to provide, promote or use ethical and reliable conformity assessment services [16].

Several ISO/IEC Guides are related to production certification. In particular, ISO/IEC 17067:2013 (Conformity assessment – fundamentals of product certification) gives guidance on product certification systems by identifying their various elements based on current practices. It is intended for use by product certification bodies and other interested parties wishing to understand, develop, establish or compare third-party product certification systems. This Guide is not intended to describe all existing forms of product certification. It does not address first- and second-party product conformity assessment [16].

Many variants exist. For example, product certification may consist of initial testing of a product combined with assessment of its supplier’s quality management system. This may be followed up by surveillance that takes into account the supplier‘s quality management system plus testing of samples from the factory and/or the open market. Other product certification schemes comprise initial testing and surveillance testing, while still others rely on the testing of a sample product – this is known as type testing [16].

ISO/IEC TR 17026:2015 (Conformity assessment – guidance on a third-party certification system for products) offers general rules for a model third-party certification system for products. ISO/IEC 17065:2012 (General requirements for bodies operating product certification systems) states the general requirements that a third party operating a product certification system must meet if it is to be recognized as competent and reliable [16].

ISO/IEC TR 17026:2015 (Conformity assessment – guidance on the use of an organization's quality management system in product certification) outlines a general approach by which certification bodies can develop and apply product certification schemes utilizing requirements of an organization's quality management system.

The provisions given are not requirements for the accreditation of a product certification body and do not substitute the requirements of ISO/IEC 17065 [16].

4.5. Accreditation

Accreditation and certification are often confused or seen as equivalent, which is a misconception. Accreditation is much more than a certification. Although some procedures are similar, an accreditation contains an additional component which can be derived from the word itself: to give "credit" requires first to find out if the person, institution or laboratory is creditworthy, i. e. can be trusted regarding its competence. This cannot be noticed by just following a checklist to confirm compliance with a standard. To prove technical competence it is essential to assess not only the correct implementation of the quality standards but also to evaluate the capabilities and the technical results. A technical consultant needs to be an expert in the field of assessment with at least the same level of competence as the assessed entity so as to be able to confirm not only conformity with standards, but also the technical competence mentioned in article 6.1.1 of the WTO TBT Agreement [28].

Accreditation is a term sometimes wrongly used as a synonym for certification or registration. In fact, accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Accreditation system

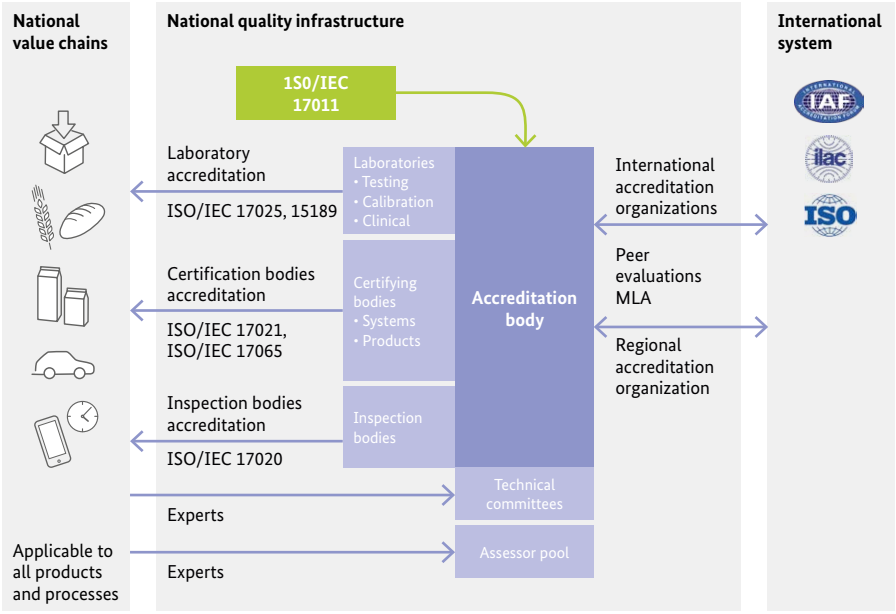


Figure 30

Accreditations are granted in many different fields. A typical structure of an accreditation body might comprise departments for the accreditation of:

- Testing and calibration laboratories according to ISO/IEC 17025
- Inspection bodies according to ISO/IEC 17020
- Certifying bodies for quality management systems according to ISO/IEC 17021
- Certifying bodies for environmental management systems according to ISO/IEC 17021
- Certifying bodies for product certification according to ISO/IEC 17065
- Certifying bodies for person certification according to ISO/IEC 17024. [28]

The accreditation body itself must maintain conformance with ISO/IEC standard 17011 (Conformity assessment – general requirements for accreditation bodies accrediting conformity assessment bodies). This standard substitutes former Guides 58 and 61.

All types of accreditation, although they are conducted according to different guidelines, follow the same pattern. It consists mainly of an assessment of the implemented quality system in the entity to be accredited and an evaluation of the professional competence in the area of accreditation. For the second part, a recognized expert is generally subcontracted to join the assessment team. This gives the accreditation body an immense flexibility and the opportunity to extend its accreditation activities to every new field by always adding new recognized experts to the "consultant pool". Similar to the work of a standards body, an accreditation body operates technical committees with external experts as know-how support for the different fields of accreditation scopes.

Laws or decrees of any ministry can recognize test results of a given laboratory, but this will only be accepted on a national level. Non accredited international recognition requires regular inspections by the importing countries according to their rules, and this can result in the need for maintenance of several parallel quality structures to satisfy all kinds of inspectors.

A similar problem arises on the national level if one laboratory performs for example the same chemical analysis for clients from different sectors, e.g. for industry, environmental surveillance, health issues or food safety aspects. Should this laboratory maintain four different types of surveillances or accreditations with parallel quality systems, which would be very costly, just to satisfy four different ministries? Accreditation by one body recognized worldwide would reduce these efforts to a minimum.

The policy of the regional organizations is to have only one accreditation body per country in the MLA. Countries generally tend to establish a national accreditation system and define the structure in a National Accreditation Act to avoid competing entities and recognition complications within the country, as well as to reduce costs for duplicating national structures and for international memberships and representations. The solution is one National Accreditation Body for all fields of accreditations.

An accreditation body must be absolutely independent and impartial and it must mainly be able to be a good organizing, administrative and managing organization, which can be run with a small staff. All technical expertise is then subcontracted depending on the actual needs. Availability of experts in all possible accreditation scopes as permanent staff within an accreditation body is extremely costly and not efficient. Therefore, a lean-structured accreditation body is able to cover all national accreditation demands and, once international recognition has been achieved, can easily extend its accreditation activities to new fields [28].

Small economies with low accreditation demand will suffer from two main problems:

- insufficient income to sustain the accreditation body; permanent subsidies from the government will be necessary to maintain the accreditation body,
- due to lack of practice, the consultants will probably never gain the same experience and technical competence as their counterparts in larger accreditation bodies.

Based on experiences around the world, an accreditation body should have accredited approximately 200–300 entities to count on expertise and economic stability for international recognition. Other options are:

- set up a small office only, as a focal point and collaborate with accreditation bodies from neighbouring countries, already ILAC-MLA recognized,
- set up a regional network of complementing capabilities, with exchange of consultants and expertise,
- set up a regional accreditation body,
- set up an accreditation body for national purposes and collaborate for internationally recognized accreditation with an ILAC-MLA recognized accreditation body from another country.

Accreditation can be expensive. However, it should be kept in mind that, in the long run, the lack of accreditation and its concomitant lack of proof of technical competence and thus of trust, will turn out to be much more expensive for everyone.

Relevant to trade issues are accreditations of testing and calibration laboratories whose calibration certificates or test reports need to be recognized abroad (to avoid costly repetition of the same test), or accreditations of certification bodies where management systems and especially product certificates need to be recognized by the importing countries. In the agricultural and food processing sector particularly, mutual recognition of product certificates is essential. Frequent rejection of foodstuff on EU, USA or other countries' borders and the implementation of rapid alert systems for agricultural products show very clearly how many deficiencies still exist until a worldwide "one-stop test or certificate" becomes reality [28].

Mutual recognition plays an increasingly important role in accreditation. Clients of accreditation bodies are laboratories and certification bodies. Most of these are not able to establish individually mutual recognition agreements with their counterparts all over the world. Being recognized worldwide by only one accreditation is much simpler, easier and less costly to achieve and maintain. This requires a lean accreditation structure to facilitate mutual recognition agreements. The structure of the accreditation system is similar to that of metrological system with its regional organizations and one international umbrella organization [28].

Adoption of an international standard, called ISO/IEC 17025, as the basis for the accreditation of testing and calibration laboratories, has helped countries adopt a uniform approach to determining laboratory competence. This uniform approach allows countries with similar accreditation systems to establish agreements between themselves, based on mutual evaluation and acceptance of each other‘s accreditation systems [2].

Such international agreements, usually called Mutual Recognition Arrangements (MRAs), are crucial in enabling test data to be accepted between these countries. In effect, each partner in such an arrangement recognizes the other partner‘s accredited laboratories as if they themselves had undertaken the accreditation of the other partner‘s laboratories [2].

In addition to an accreditation, participation in proficiency tests must be obligatory. A proficiency test means a comparison of test results issued by a number of laboratories analyzing the same sample. The evaluation consists of a comparison of the mean values and the stated uncertainties. If results deviate from a tolerable range, the reliability of the laboratory is questionable and corrective actions have to be taken [28].

Accreditation is based on peer evaluation

ILAC/IAF

Peer evaluation leads to worldwide MLA

APAC, EA, IAAC

Peer evaluation leads to regional MLA

National accreditation bodies

The regional forum for laboratory accreditation in Asia is called Asia Pacific Accreditation Cooperation (APAC), which is already a merger from former Asia-Pacific Laboratory Accreditation Cooperation (APLAC) and the parallel structure for the accreditation of certification bodies called Pacific Accreditation Cooperation (PAC). The regional forum for laboratory accreditation in Asia is called the Asia-Pacific Laboratory Accreditation Cooperation (APLAC). There still exists a parallel structure for the accreditation of certification bodies called Pacific Accreditation Cooperation (PAC).

The international umbrella organizations are the International Laboratory Accreditation Cooperation (ILAC) for the accreditation of laboratories and the International Accreditation Forum (IAF) for the accreditation of certification bodies. The concept of a lean worldwide recognition is based on mutual recognition agreements within the regions and, in a second step, between the regional organizations by Multilateral Arrangements (MLA), to reduce the always necessary mutual assessments of equivalence.

With reference to regional accreditation organizations such as APAC, EA and IAAC, mutual recognition of the national accreditation bodies is achieved by peer assessments of counterpart accreditation bodies from the region to confirm equally good performance. The more accreditation bodies participate, the more assessments and coordination are required and have to be coordinated by the regional accreditation organization.

If the regional accreditation organization (APAC, EA, IAAC) is already recognized by ILAC, a peer evaluation within the regional accreditation organization leads not only to a regional MLA but includes automatically the ILAC MLA.

Part 5 – Integration of the Components into a National Quality Infrastructure (Systemic Approach)

The **MSTQ** concept (metrology, standardization, testing and quality management) has evolved to the more integrated Quality Infrastructure (QI) concept. This is truly a more holistic approach where the whole is more than just a collection of parts added together.

The several components mentioned previously – standardization, metrology, testing, certification, accreditation – comprise a National Quality Infrastructure (QI). This infrastructure can be used for all products and services and it ensures that they will comply with the requirements of the clients, either consumers, manufacturers or regulators.

The consumer wants a product backed by some sort of certificate so he will know the product conforms to given standards. This requires the producer to have in place a system of quality management and of conformity of his product with given standards; this is guaranteed by a certification process.

National quality infrastructure

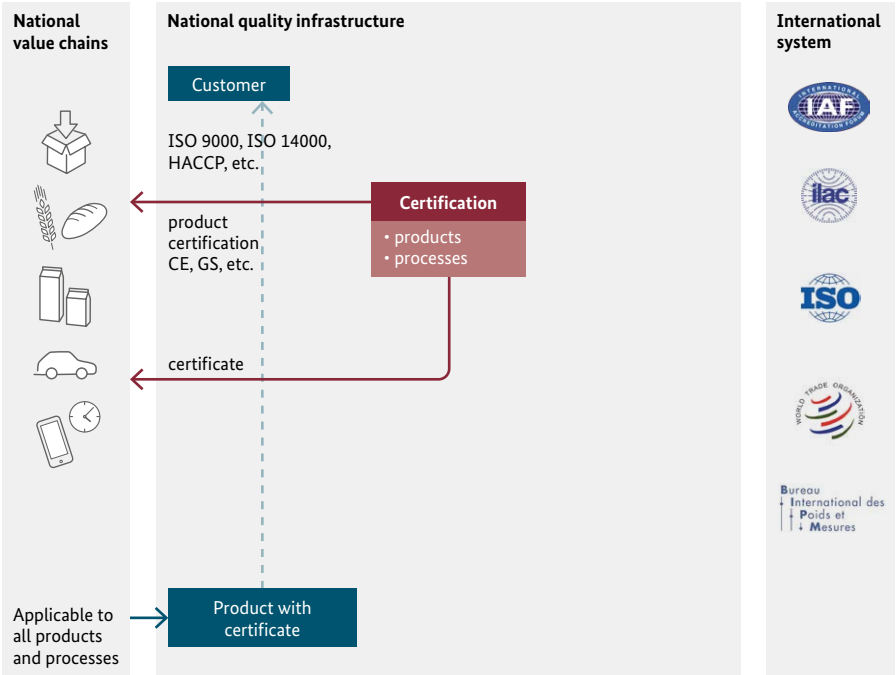


Figure 31

National quality infrastructure

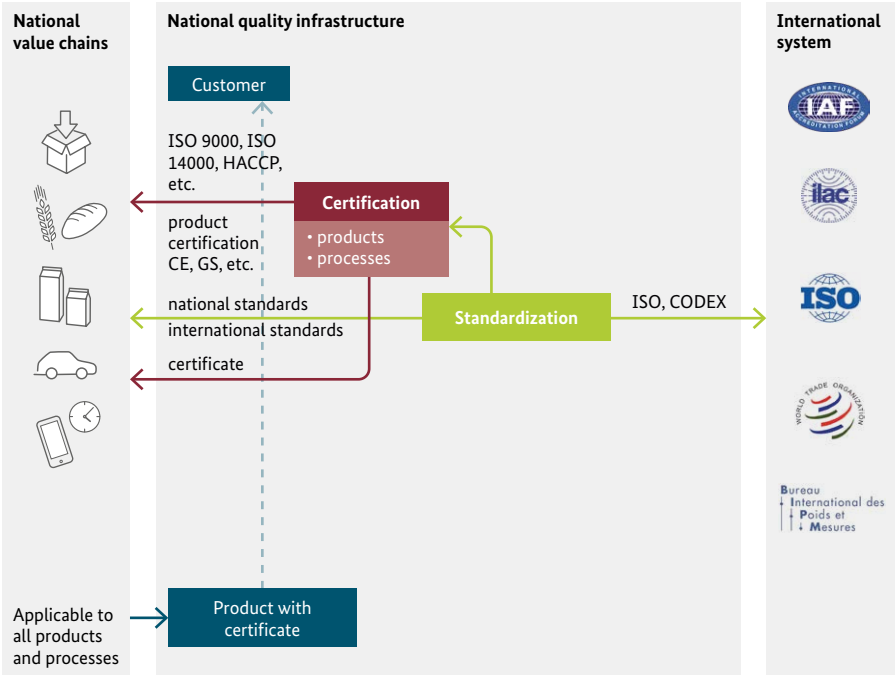


Figure 32

To ensure the certificate is recognized and harmonized with regional or international conditions, certification must follow existing standards and this, in turn, requires a functional standardization component.

National quality infrastructure

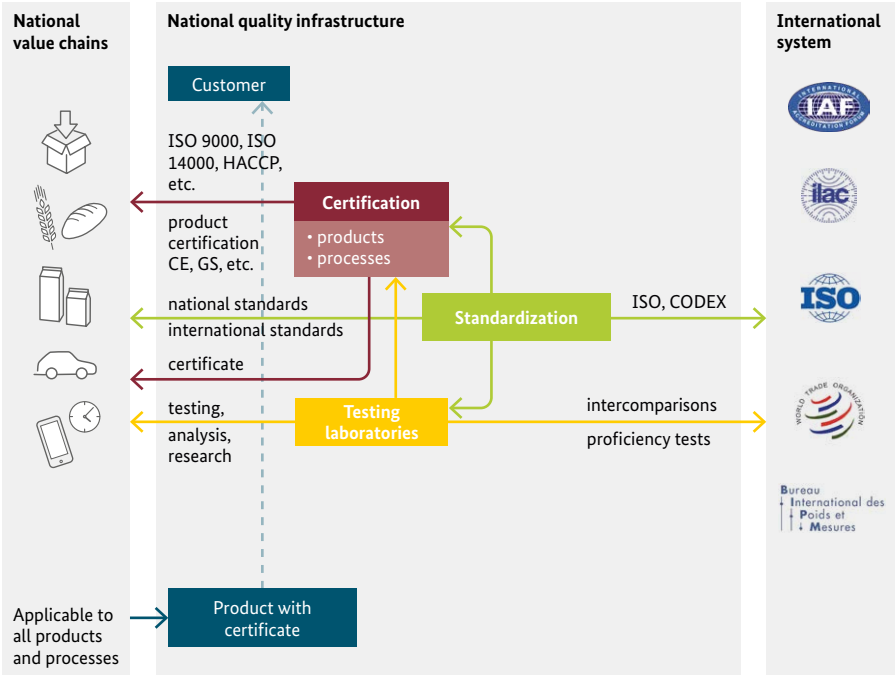


Figure 33

On the other hand, in order to be backed by a certificate, a product must be tested to determine if it effectively conforms to the appropriate standards. This requires testing laboratories that will carry out their tests and analyse according to accepted international standards.

National quality infrastructure

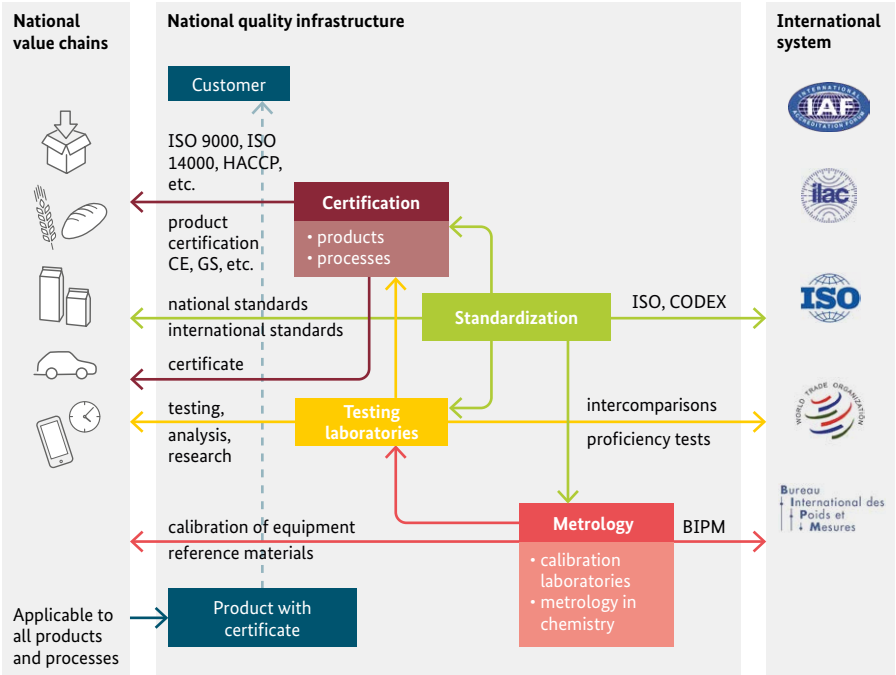


Figure 34

The testing laboratories must be able to show that their measurements are reliable, meaning they can be traceable to national measurement standards and, through these, to international measurement standards. Also, equipment must be properly calibrated if the testing results are to be trusted. The National Metrology Institute and the calibration laboratories can give this support to the producer.

National quality infrastructure

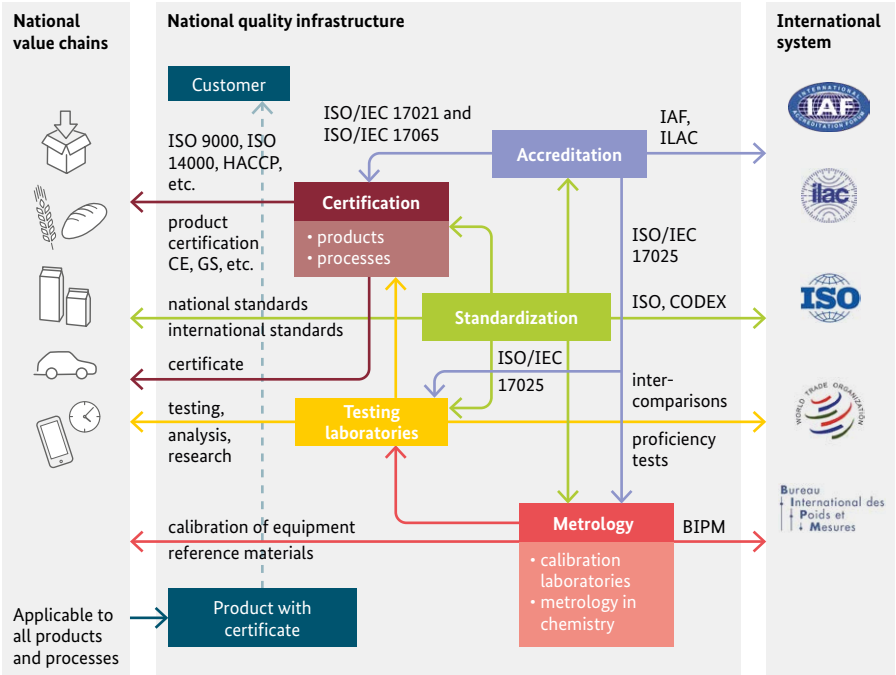


Figure 35

Technical competence of the laboratories and of the certification bodies is confirmed by accreditation bodies thus giving confidence to all involved parties that the whole process can be trusted.

Part 6 – A Case of QI Application to a Productive Chain

National quality infrastructure

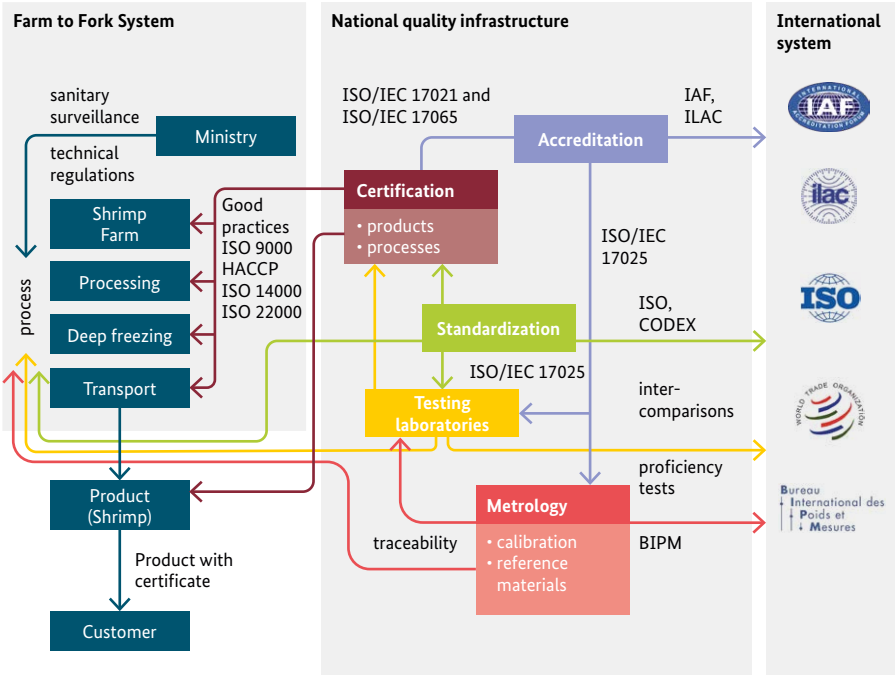


Figure 36

We have described in detail the national quality infrastructure in previous sections. Let us now look at the left-hand side, that is, at a production chain and to the application of the national quality system to this production chain. We call this side of the figure a “farm to fork” system because we will be following a food product – shrimp in this particular case – from its production to its purchase by the consumer.

National quality infrastructure support

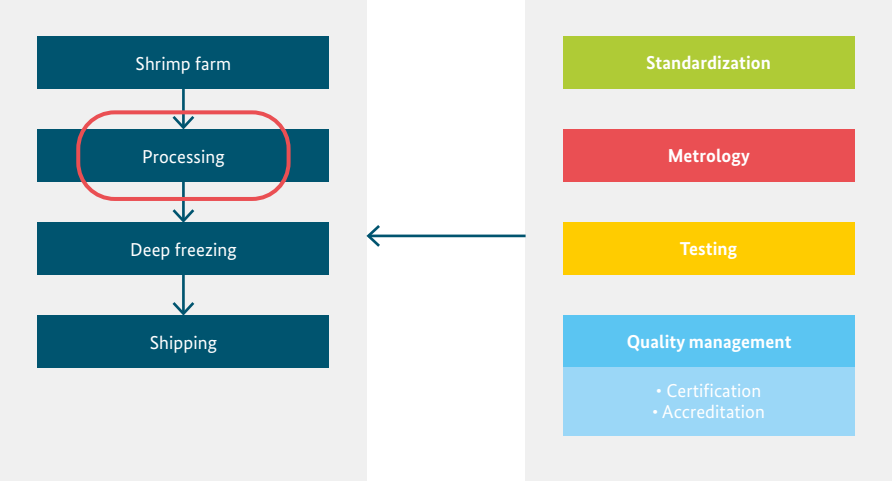


Figure 37

During the production process, from raw material to the final certified product, all involved actors in the chain have to comply with certain requisites that can be mandatory (e.g. regulations on food safety) or additional client requirements (e.g. bio-standards) for access to specific markets.

The national quality infrastructure can be considered competent only if it has developed and can provide the required services. When these are not directly available in the country because of, for instance, lack of resources or of a critical mass to justify development, the QI gives the necessary support to local consumers by means of regional networks, outsourcing or facilitation.

Let us see what has to be considered
There may be several ministries involved in controls for the shrimp industry. Health – with its consumer health-protection legislation, agriculture – as in several countries it controls all food production, environment – to ensure that shrimp catching or farming does not negatively affect the environment.

Technical regulations to be complied with by the shrimp farmer may consider aspects such as:

- restrictions on the amount and size of shrimp nauplii[1], postlarvae, juveniles and gravid shrimp caught in estuaries and in the wild,
- in many countries, it is illegal to build new shrimp farms in tidal and mangrove areas,
- allowable levels of effluents (shrimp waste products, uneaten feed, dead algae and bacteria),
- allowable levels of naturally-occurring chemicals,
- allowable levels of additives,
- allowable levels of harmful chemicals that can produce acute or chronic illnesses,
- labeling; legislation requires that each product be labeled with:
  - true description of the goods,
  - list of ingredients in descending order,
  - net contents,
  - date of packaging or processing,
  - registered establishment number,
  - country of origin,
  - identification of lot,
  - method of preservation,
  - name and address of the manufacturer, producer, exporter or consignee.

When exporting, the shrimp must also comply with the requirements of the importing country:

- product standards,
- hygiene and operational requirements,
- specific analysis to demonstrate conformity,
- prescribed methods for microbiological, chemical or physical examination of the products by reference to appropriate standards.

1 Nauplii are tiny, newly-hatched, first-stage larvae

The shrimp farm may also be required to submit to a HACCP audit. This "Hazard Analysis and Critical Control Point" is a systematic approach to the identification, evaluation and control of food safety hazards. It promotes international trade by increasing confidence in food safety and is based on the following seven principles:

- conduct a hazard analysis (biological, chemical or physical),
- determine the Critical Control Points (CCPs). A CCP is a point, step, or procedure where it is possible to prevent or eliminate a food safety hazard, or reduce it to acceptable levels,
- establish critical limits for preventive measures. There are boundaries of safety for each CCP, e.g. time, temperature, humidity, pH, titratable acidity, preservatives, salt concentration and viscosity,
- establish procedures to monitor CCPs,
- establish corrective action to be taken when monitoring shows that a critical limit has been exceeded,
- establish procedures to verify that the HACCP system is working,
- establish effective record keeping systems that document the HACCP system.

Buyers may also require the farm to comply with farm certification standards such as, for instance, those set up by The Global Partnership for Safe and Sustainable Agriculture, an entity that seeks that food be produced respecting worker health, safety and welfare, as well as environmental and animal welfare issues. This might involve aspects such as control points and compliance criteria for food producers and feed manufacturers and the chain of custody.

The shrimp farm also needs extensive testing and measurements; if it does not have its own facilities it will have to rely on outside bodies for:

- control of water quality variables,
- control of stocking densities,
- control of aeration,
- analysis of feeds and fertilizers,
- dosage of feeds and fertilizers (fertilizers are used to stimulate the natural food chain),
- weight of post-larvae from nurseries before moving them to grow-out ponds,
- ponds salinity and temperature,
- control of diseases (fungi, bacteria, virus).

During processing, standards to be applied may address:

- reception, grading, weight, packaging and freezing,
- in some cases, beheading, deveining and peeling,
- possible contaminants during the processing itself,
- when shrimp is sold precooked, controlled temperatures and pressure,
- compliance of premises with requirements outlined in legislation such as:
  - structural requirements for factory or vessel,
  - maintenance and operation in a hygienic manner,
  - principles of good manufacturing practice, e.g. temperature control, layout of facility, positive air pressure that are essential for product safety.

During deep freezing, reliable measurements of temperature and time are crucial for proper maintenance of shrimp tissue and to control icing.

Example: Processing – necessary services from national quality infrastructure

Processing chain

1 . Raw shrimp
- Sizing
- Sulfite/antibiotic residue
- Any defects, contaminants

2. Washing
3. Draining/weighing
4. Washing
5. Keeping in cold water
6. Beheading/peeling/deveining/washing
- Check temperature (shrimps, washing water)

7. Soaking with dry ingredients
- Check temperature (shrimps)

8. Sizing
- Check size

9. Arranging
- Check temperature (shrimps)

10. Cooking
- Check boiling temperature, time, physical properties

11. Cooling/separating defects/trimming
- Check temperature of cooling tank, shrimps

12. Freezing (N_2 freezer)
13. Weighing/glazing
- Check weight, temperature
- Check product size after freezing

QI support

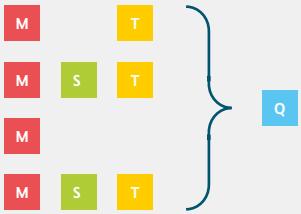


Figure 38

Processing: Quality requirements for "cooking"

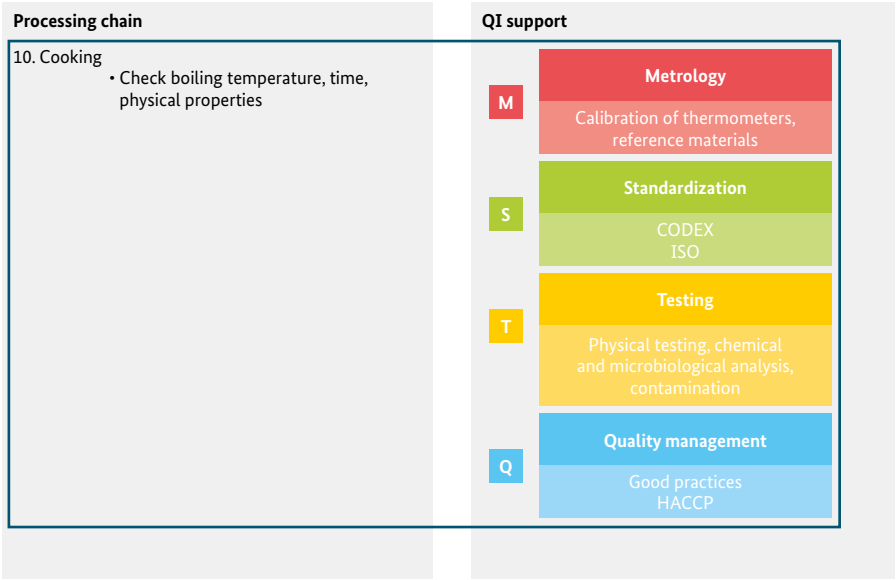


Figure 39

Temperature has also to be reliably measured during transportation and in cold stores. Products directed for storage or to a purchaser may be randomly checked by the internal quality control staff. This involves:

- proper packaging materials and labeling,
- proper conditions, e.g. temperature of transport and storage facilities and duration of these activities,
- hygienic conditions during transport (cleanliness, temperature records, correct loading in vehicles).

The shrimp farm may strive for certification under ISO 9000 (a quality system) and ISO 14000 (an environmental management system), and also for a certification of compliance with product standards and technical regulations. This represents a market advantage for the producer as the customer is assured of receiving a high-quality product.

At an FAO workshop held during the Bali 2005 World Aquaculture Society meetings, a variety of new programmes for the shrimp industry were discussed including: Global Aquaculture Alliance Responsible Aquaculture Program (Aquaculture Certification Council), Safe Quality Food (SQF) Shrimp program, Organically Certified Shrimp, Fair Trade Shrimp, EurepGap (European retail) and British Retail Consortium, Bangladesh Shrimp Seal of Quality, Thai Quality Shrimp programme, World Wildlife Fund and Environmental Justice Foundation (EJF).

EurepGAP, the private voluntary certification program set up by large supermarket chains in Europe differs from other certification programs in that it emphasizes sanitary production conditions and traceability of the product to its origin, in this case the particular shrimp farm. It is expected that in the future, participants in this program will require EurepGAP certification to place the products on the shelves of their supermarkets.

This example shows in how many aspects QI services play an important role. If not available in a country, or if not internationally recognized, the results will be additional costs or loss of market access.

The value chain approach for a specific product of national interest is helpful in analyzing and evaluating the services provided by the national QI. For every step from the raw material to the final product – farm to fork – this approach includes the detailed analysis of which government offices are involved, what are the requirements on standards, metrology, testing laboratories, calibration, reference materials, certification bodies, accreditation, etc, and which of these are covered by the national QI, the role of international cooperation, and the necessary coordination.

Too often, the QI components exist in general but the required standard may not be available, the necessary test is not offered or it is offered but this particular parameter is not accredited. Or, in spite of having a **NMI**, the calibration range needed has no traceability, the reference material is not certified or the certifier has no accreditation.

A sound analysis of the quality services required in the value chain will lead to clear recommendations to the responsible actors in the QI for the improvement or development of services.

A working group consisting of all stakeholders such as producers, ministries, standards body, **NMI**, testing laboratories, certification and accreditation bodies, can analyze the QI requirements in all steps of the chain and verify that the relevant services are existing, accessible, reliable and internationally recognized. International technical cooperation may step in to support national efforts.

National quality system for an agricultural product

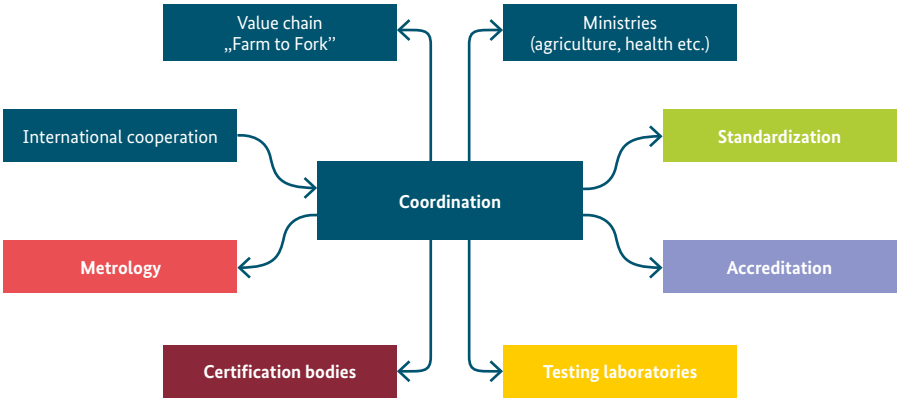


Figure 40

Part 7 – Some Recommendations Based on Experience

7.1. National law on quality

The purpose of a national law on quality is to set up the national quality system as the infrastructure in charge of developing and promoting quality, promoting competitiveness in local enterprises, to make transactions of goods and services more trustworthy, facilitate compliance with international agreements pertaining to conformity evaluation, give technical support to regulators [3].

Laws and regulations are addressed to the general public and to the courts of law and as such they must be written in the language approved by legal authorities of the country.

There usually is a fairly long time between formulation of a law and its being in effect, and thus it is recommended to promote a simple basic law model and cover further details in regulations as these are easier to approve and/or modify [23].

Key aspects to be considered for the legal framework are:

- the policy for the development of the national quality infrastructure, the adjustments of the services to national needs, and assuring the functioning and the stability of the system. These should be steered by a National Quality Council; its members should be the relevant heads of ministries from the public sector, and representatives from private sector groups such as chambers of commerce or exporters, industry associations, academe and consumer protection. The balance of power between private and public sectors is indispensable for wide acceptance,
- creation of national standards body, national metrology institute, and national accreditation body as absolutely independent and impartial entities with the autonomy and financing necessary to comply with their national and international technical tasks,
- definition of functions and tasks as much as possible with reference to international guidelines and practices. Changes in these guidelines will then not require changes in the law itself,

- the three bodies might operate under one roof to increase administrative efficiency and to reduce costs but in this case clear firewalls for decisions, personnel, bank accounts etc., must be assured to avoid any conflict of interests as may happen if only one executive director is responsible for the three areas. Administration should be understood as the service provider and facilitator for the technical institutes and not as a decision maker,
- each institute should have an executive council with participation of at least fifty per cent of the private sector, to filter any sector motivations or political influences,
- stability of technical personnel must be guaranteed to assure continuity of technical expertise and development.

7.2. Inter-relationships between voluntary and mandatory aspects, functions of regulating bodies

Bodies in charge of regulatory aspects have as their main task to supervise and ensure that the system works.

It is neither necessary nor convenient for the regulating bodies to try to carry out themselves all required tasks; this would mean unnecessary duplications and expenses. It is preferable for them to delegate certain activities. This is valid even when the activities refer to mandatory aspects, as long as this delegation is done to entities recognized as technically competent and is properly supervised. This will result in better support for and strengthening of the national system.

The regulatory body can use any private or public testing laboratory, inspection and certification bodies. The only condition is an accreditation by an internationally recognized accreditation body in the required field, and a registration as service provider with the regulatory body.

As an example, in some states of Germany, private companies are in charge of the control of water, gas and electricity meters. Also taxis have to go to private enterprises, duly recognized and supervised by the official metrology body, for control of brakes and taximeters.

7.3. Use of the quality infrastructure by regulating bodies

The conformance risks spring mainly from increasing concerns about product safety, labor standards and environmental standards; producers in developing countries are expected to meet requirements that frequently do not (yet) apply to their domestic markets. This creates a gap between the capabilities required for the domestic market and those required for the export market. Therefore, parameter setting and enforcement may be required to ensure that products and processes meet the required standards. If the gap has to be closed quickly, buyers will need to invest in a few selected suppliers of services and help them to upgrade (or rely on the regulating bodies) [18].

The corollary of this is that the need for parameter setting along the chain may decrease as the capabilities of developing country suppliers improve and diffuse. At the initial stages of a supply relationship, buyers may feel the need to provide detailed instructions and undertake close monitoring of supplier performance. As the suppliers become more experienced, and as they are able to demonstrate their reliability to the customer, the latter may begin to indicate the standards to be met, but leave it to the supplier to work out how to meet them [18].

Once parameters have been set by firms in the chain or by agents outside of the chain, how are they enforced?

Compliance with product parameters can usually be monitored and enforced through inspection and testing. This can take place at various stages, including at the design and pre-production stages, depending upon the extent to which the supplier is responsible for the design. In some cases, government agencies will also inspect products prior to their introduction in the national or regional market [18].

7.4. Public and private sectors

Buyers, mostly of the private sector, very often specify process parameters. They may also be deeply involved in their supplier's quality systems and in specifications of process parameters in relation to labor and environmental standards. In some cases, the buyer may merely refer to the process standards to be attained. In other cases, the buyer will specify precisely how particular standards should be attained by requiring and perhaps helping to introduce particular production processes, monitoring procedures, etc. [18].

On the other hand, government agencies and international organizations regulate product design and manufacture, not only with a view to consumer safety, but also in order to create transparent markets (for example, by defining standard weights and sizes or technical norms). Examples of such parameter setting by agents external to the productive chain include food safety standards, norms with regard to the safety of products such as children's toys, electrical equipment and motor vehicles and control of hazardous substances in a wide range of products. Once again, these norms can refer to the product (are its physical characteristics and design in conformance with requirements?) or to the process (is it being produced in ways which conform to particular standards?). In some cases, process norms are pursued as a means to achieving product standards (for example, hygienic food preparation systems are designed to produce safe food) and in others because of the intrinsic value of particular types of processes (for example, animal welfare requirements).

Governments may set standards that are compulsory and have legal force and which are then called technical regulations. Standards may also be set by non-legal agreements (code of conduct, etc.) and by a variety of unofficial agencies, such as NGOs, that put pressure for compliance with labor and environmental standards [18].

Firms are expected not to use suppliers that employ child labour, but this expectation is not accompanied by any system for enforcing the ban. The firms have to develop their own enforcement systems.

The EU requires that surgical instrument manufacturers exporting to the European market must be ISO 9000 certified. This certification is carried out by independent certification agencies.

The US Department of Agriculture (DoA) requires certain regions exporting melons to the US market to have a State administered fruit-fly monitoring and eradication program which has to be approved by the Department of Agriculture [18].

Thus, one agent in the value chain either enforces compliance with parameters of other agents, or translates these parameters into a set of requirements which it then monitors and/or enforces [18]; this is particularly true in global value chains.

These "others" might be other agents within the chain (for example, UK supermarkets requiring their importers to monitor the quality systems of horticultural producers and exporters), or third party specifically hired for the task, as happens when NGOs or independent monitors are hired by companies to verify labor standards at suppliers. The key point here is not whether the firm or an agent does this work, but that the firm defines the parameters to be met and arranges for compliance to be monitored. There are cases where the parameters are specified by agents external to the chain (such as government agencies) and the monitoring processes are also in the hands of agents external to the chain. In this case, no individual firm in the chain takes responsibility for defining or enforcing the parameters; they apply to all the firms in the chain.

The decision to insist on a standard is made by the lead firm (it is not imposed from outside), but if the standard is widely known and adopted, then it is likely that organizations (standards agencies, consultancy firms, etc.) exist both to certify companies and to help firms meet the specified standard [18].

For this process to take place, it is necessary for the parameters being specified to be widely applicable across different firms and to have credible means of external monitoring and enforcement. It may be the case that in the early stages of the development of new process parameters, such as labor standards, these are initially enforced by lead firms within the chain. As standards become more generalized, then external systems of enforcement develop, such as the SA 8000 labor standard [18] of the Council on Economic Priorities Accreditation Agency (CEPAA).

If it were the case that certification systems demonstrating adherence to a range of process standards, including quality, environmental and labor standards, were developed, this might substitute for process controls by lead firms. Direct monitoring and control of suppliers could be substituted by certification processes [18].

As the competence of these suppliers increases, chain governance through the buyers can be expected to loosen – provided that the increasing competence of suppliers is accompanied by the emergence of local agents who can monitor and enforce the compliance with general or buyer specific standards.

Business-to-Business (B2B) electronic commerce is being promoted world-wide as a means of enabling developing country producers to sell in advanced country markets and transform the relationship between producer and buyer; all forms of e-procurement are likely to require mechanisms to contain buyer risk, such as certification. Monitoring and accreditation agencies will be of increasing importance; there may be a shift to parameter setting and enforcement **by agents outside the chain**, i. e. mediators. The more conformance/compliance with parameters can be codified, generalized and credibly applied, the less need there is for governance from within the chain [18].

7.5. Alliances and networks

Regional cooperation promotes the mutual recognition of national structures (and standards) and thus breaks down technical barriers to trade. If an institutional infrastructure is to be built up from scratch, it often makes more sense to do so in a complementary way through regional groupings and to use it jointly (one example is expensive laboratory equipment). This can lend impetus to the process of regional integration [13].

Greater use should be made of the sector's potential to foster regional integration processes. Action is demanded from the partner countries in terms of spreading and implementing regional trade agreements; the way to do this is through regional cooperation. As an example, German development cooperation is already promoting the joint use of national structures that have been developed in a complementary way; it must however take account from the outset of the fact that regional coordination processes take more time [13].

For instance, in the specific case of chemistry, implementation of a national infrastructure is challenging due to the huge amount of chemical parameters, and to set priorities requires good knowledge of the demand, which is generally related to export goods, environment and health. The development of the entire chemical infrastructure in only one institute, as is frequent for physical quantities, is practically an illusion. The trend in many countries is to incorporate technical capabilities already existing and to establish a network of National Reference Laboratories to cover all the important parameters. The National Metrology Institute as the only signatory to the BIPM-MRA (Multilateral Recognition Agreement) has to be the internationally recognized coordinator while the technical competence for the national and international tasks pertains to the designated National Reference Laboratories [28].

The primary objective is to give users confidence that requirements applicable to products, services, systems, processes and materials have been met. One of the reasons why internationally traded goods and services are subject to repeated conformity assessment controls is a lack of confidence by users in one country regarding the competence of bodies carrying out these activities in other countries.

Therefore, measures are needed to increase the confidence of both private and public sector purchasers, and of regulators, in the work of conformity assessment bodies and accreditation bodies – particularly those in other countries [16].

Mutual Recognition Agreements (MRAs) and Multilateral Recognition Arrangements, (MLAs), seek to provide users with the assurance that equivalent bodies in other countries operate to the same standard as those in their own country.

International experts may subject the MRA/MLA members to rigorous operational evaluations before and during their MRA/MLA membership to ensure that high standards are maintained. This reduces costs and adds value to industry and consumers [1].

BIPM-MRA

In 1999 the CGPM implemented the **Mutual Recognition Arrangement** (MRA) to achieve more transparency and equivalence between National Metrology Institutes. It is administrated by BIPM.

The MRA is based on verified information about the participating NMIs, documented in KCDB Key Comparison Data Base (*www.bipm.fr*):

- participating institutes,
- results of key comparisons and supplementary comparisons,
- best measurement capability,
- uncertainty,
- information about implementation of quality system.

As an example, Annex 4 lists the CCQM key comparisons areas for chemistry.

Certificates in the fields of management systems, products, services, personnel and other similar programs of conformity assessment issued by bodies accredited by IAF MLA members are also relied upon in international trade.

The mechanism by which IAF implements its objective is the IAF Multilateral Recognition Arrangement (MLA). Accreditation body members of IAF are admitted to the MLA only after a most stringent evaluation of their operations by a peer evaluation team which is charged with ensuring that the applicant member complies fully with both the international standards and the IAF requirements. Once an accreditation body is a member of the MLA it is required to recognize the certificates issued by certification/registration bodies accredited by all other members of the MLA [1].

7.6. International recognition

The national quality system of a country should seek international recognition so that verification of the quality of its products and services does not become a technical barrier to its trade.

Whenever standards are not specified by the supplier or buyer but rather developed locally, they, and also technical regulations, must be coherent with international requirements.

For metrology, it is possible to establish regional mutual recognition agreements (CIPM-MRA, MLAs) and the national metrology laboratory or institute must be accredited by an ILAC member. One can also envisage a virtual national metrology institute, through a network of national reference laboratories, delegating functions for given areas and magnitudes as is done in countries such as France, Germany, and Spain.

Internationally recognized accreditation of testing laboratories and of certifying bodies is also a requirement for results to be accepted throughout the chain and for the One-stop test to achieve worldwide acceptance to become a reality.

Accreditation can be carried out at lower costs if the national body works as a “branch” of a recognized entity.

The need for the One-stop test to achieve worldwide acceptance
A CASE: An instrument with state-of-the-art capabilities and barely three or four competing instruments worldwide, was calibrated and traceable to NIST in the USA. However, Canadian non-tariff trade standards required traceability to NRC in Canada. NRC calibration merely verifies conformity to NRC measurements, it does not improve the quality of the instrument or the uncertainty of its measurements in any way. This process is costly, and it introduces significant delays in delivery. Both buyer and seller had nothing to gain from it [32].

Annex 1 – Acronyms and Abbreviations

ACCSQ	ASEAN Consultative Committee on Standards and Quality
AFTA	Asian Free Trade Agreement
APAC	Asia Pacific Accreditation Cooperation
APEC	Asia-Pacific Economic Cooperation
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
APMP	Asia Pacific Metrology Program
ASEAN	Association of Southeast Asian Nations
BIPM	Bureau International des Poids et Mesures, *www.bipm.org*
CCP	Critical Control Points
CCQM	Consultative Committee for Amount of Amount of Substance
CE	Communauté Européenne
CE	European Union Compliance Mark
CGPM	Conférence Générale des Poids et Mesures
CIPM	Comité International des Poids et Mesures
CMC	Calibration and Measurement Capabilities
COPANT	Comisión Panamericana de Normas Técnicas, *www.copant.org*
CRM	Certified Reference Materials
EA	European Cooperation for Accreditation, *www.european-accreditation.org*
EAC	European Accreditation of Certification
EAL	European Cooperation for Accreditation of Laboratories
EU	European Union, *www.europa.eu*
EurepGAP	Euro Retailer Produce Working Group – Good Agricultural Practice; The Global Partnership for Safe and Sustainable Agriculture, *www.eurepgap.org*
FAO	Food and Agriculture Organization, *www.fao.org*
FDA	The Food and Drug Administration, USA, *www.fda.gov*
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practice
GS	Safety Certification
HACCP	Hazard Analysis Critical Control Points
IAAC	Inter-American Accreditation Cooperation, *www.iaac.org.mx*
IAF	International Accreditation Forum, *www.iaf.nu*
IEC	International Electrotechnical Commission, *www.iec.ch*

ILAC	International Laboratory Accreditation Cooperation, *www.ilac.org*
ISO	International Organization for Standardization, *www.iso.org*
JCDCMAS	Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization
KCDB	Key Comparisons Data Base
MLA	Multilateral Arrangement
MRA	Multilateral Recognition Agreement
MSTQ	Metrology, standardization, testing, quality management, accreditation, conformity assessments including certification
NGO	non-governmental organization
NMI	National Metrology Institute
NNA	National Notification Authority
OAS	Organization of the American States, *www.oas.org*
OIML	Organisation Internationale de Métrologie Légale, *www.oiml.org*
PAC	Pacific Accreditation Cooperation, *www.apec-pac.org*
PAHs	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
PM	Primary methods
PT	Proficiency tests
PTB	National Metrology Institute, Germany, *www.ptb.de*
RMO	Regional Metrology Organizations
SI	International System of Units
SIM	Sistema Interamericano de Metrología / Interamerican Metrology System, *www.redhucyt.oas.org/SIM*
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
UE	Union Européenne, *www.europa.eu.int*
UNIDO	United Nations Industrial Development Organization, *www.unido.org*
VDE	Association for Electrical, Electronic and Information Technologies, Germany, *www.vde.de*
VDE	Electrical Equipment Quality Mark
WHO	World Health Organization, *www.who.org*
WTO	World Trade Organization, *www.wto.org*

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Annex 3 – Metrology in Chemistry

List of CCQM measurement categories for amount of substance:

1. High purity chemicals
   - 1.1. Inorganic compounds
   - 1.2. Organic compounds
   - 1.3. Metals
   - 1.4. Isotopics
   - 1.5. Other

2. Inorganic solutions
   - 2.1. Elemental
   - 2.2. Anionic
   - 2.3. Other

3. Organic solutions
   - 3.1. PAH's
   - 3.2. PCB's
   - 3.3. Pesticides
   - 3.4. Other

4. Gases
   - 4.1. High purity
   - 4.2. Environmental
   - 4.3. Fuel
   - 4.4. Forensic
   - 4.5. Medical
   - 4.6. Other

5. Water
   - 5.1. Fresh water
   - 5.2. Contaminated water
   - 5.3. Sea water
   - 5.4. Other

6. pH

7. Electrolytic conductivity

8. Metals and metal alloys
   - 8.1. Ferrous metals
   - 8.2. Non-ferrous metals
   - 8.3. Precious metals
   - 8.4. Other

9. Advanced materials
   - 9.1. Semiconductors
   - 9.2. Superconductors
   - 9.3. Polymers and plastics
   - 9.4. Ceramics
   - 9.5. Other

10. Biological Fluids and materials
    - 10.1. Blood, plasma, serum
    - 10.2. Urine fluids
    - 10.3. Hair
    - 10.4. Tissues
    - 10.5. Bone
    - 10.6. Botanical materials
    - 10.7. Other

11. Food
    - 11.1. Nutritional constituents
    - 11.2. Contaminants
    - 11.3. GMO's
    - 11.4. Other

12. Fuels
    - 12.1. Coal and coke
    - 12.2. Petroleum products
    - 12.3. Bio-mass
    - 12.4. Other

13. Sediments, soils, ores and particulates
    - 13.1. Sediments
    - 13.2. Soils
    - 13.3. Ores
    - 13.4. Particulates
    - 13.5. Other

14. Other materials
    - 14.1. Cements
    - 14.2. Paints
    - 14.3. Textiles
    - 14.4. Glasses
    - 14.5. Thin Films
    - 14.6. Coatings
    - 14.7. Insulating Materials
    - 14.8. Rubber
    - 14.9. Adhesives
    - 14.10. Other

Annex 4 – CCQM Key Comparison Areas

Domaines des comparaisons clés du CCQM :

Health
- health status markers (cholesterol/heart disease, diabetes/glucose, creatinine/ kidney function, trace hormones, DNA-based markers)
- electrolytes (Na, K, Ca)
- toxic substances in blood (e.g., Pb, Hg)
- anabolic steroids in urine

Food
- pesticide residues
- antibiotics in meat
- growth hormones in meat
- vitamins and minerals
- drinking water (EPA list)
- GMO

Environment
- air (EPA HAPs list)
- soil/sediments
- biological tissues
- waste water (EPA list)

Advanced Materials
- semiconductors
- metal alloys
- polymers and plastics

Forensics
- drugs of abuse
- explosive residues
- breathalyzer (ethanol-in-air)
- DNA profiling

Commodities
- emissions trading (SO_2 in stack emissions)
- sulfur in fossil fuels
- natural gas
- sucrose
- cement (Ca, Si, Al, S, Ti, Na, Mg)
- source of origin/adulteration

Pharmaceuticals
- chirality
- purity determination

Annex 5 – List of Figures

Authors

With a university degree in Biological Chemistry and further university studies in mathematics, Rocío Marbán worked for many years as an information specialist at the Central American Institute for Industry in areas related mainly to industrial processes, scientific and technical research, economic and market studies, testing laboratories, standardization and metrology.

Recently she has been mainly involved in editing and authoring technical books.

Clemens Sanetra is a multiskilled consultant as regards the different components of national quality infrastructure systems, with the main focus on metrology. He works in technical cooperation projects all over the world, mainly in Asia and Latin America.

During his studies – he received his PhD at the Institute for Fatigue Analysis and Plant Engineering at the Technical University of Clausthal in Germany – and his professional activities, he gained experience in various areas, among others material testing, environmental management, metrology in chemistry, and quality assurance in value chains. Striving to combine the different qualityrelated fields, he has developed a systemic approach towards the establishment of national quality infrastructures.

Notes

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