UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
National Metrology Institute

FOSTERING SUSTAINABILITY AND RESPONSIBLE SOCIAL AND ECONOMIC ACTION

Building legal frameworks for a future-proof Quality Infrastructure

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Federal Ministry
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and Development

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FOREWORD

In our rapidly evolving world, climate change, biodiversity loss, renewable energy demands, the Fourth Industrial Revolution, and demographic shifts are reshaping economies, environments, and livelihoods. In order to effectively address these mega-trends, it is vital first of all to accurately measure the effects that they have, and secondly to assess the impact of the actions we take in response to build resilient, climate-adaptive communities and economies.

Robust Quality Infrastructure (QI) systems are crucial for supporting governments and industries in designing and monitoring evidence-based responses to the challenges we all face. They are an integral part of sustainable eco-system management, a just energy transition, and creating fair trade relations. Sound institutional and legal frameworks, alongside effective regulations and governance mechanisms, are an essential basis upon which to build the sustainable industry of the future.

These capacities are key to improving the industrial and economic performance of countries, in turn meaning greater prosperity, health, and well-being. For more than 50 years, UNIDO has supported its Member States in improving their competitiveness through QI systems which align with national strategies to boost productive capacity, expand exports, and attract both domestic and foreign investment. A well-implemented National Quality Infrastructure (NQI) supports policy goals far beyond trade alone, playing a significant role in efficient resource use, health, environmental protection, and climate action, as well as other objectives of the Agenda 2030 Sustainable Development Goals (SDGs).

At its core, a QI legal framework provides the foundation for setting and enforcing regulations, establishing standards, and ensuring compliance. It fosters innovation, facilitates trade, protects consumers, and enhances industrial capacities. This publication highlights the crucial role that such legal frameworks play in building sustainable QI systems which address today's challenges while also fostering resilience for the future.

Moreover, strong QI legal frameworks support the creation of robust institutions responsible for standardization, metrology, accreditation, conformity assessment, and market surveillance. When standards and regulations are consistently applied due to their efforts, these institutions contribute to a stability, predictability, and conformity with standards within the broader market environment. This in turn builds both public and private trust and promotes transparency. This is an essential process for governments, businesses, and consumers alike, as it enables informed decision-making, reduces the risk of fraud, and fosters a culture of accountability – which is ultimately what attracts investors from around the world to build further, lasting prosperity.

By ensuring that products and services are safe and reliable, QI protects consumers and enhances public health. By securing access to such products and services for all parts of the population, it also helps to reduce socio-economic inequalities. However, QI helps not only people, but also planet. Climate change, biodiversity loss, and environmental degradation are pressing global challenges that require coordinated and combined efforts. An appropriate QI legal framework means economic activities do not harm the environment contributes to the transition toward a greener economy.

The importance of a QI legal framework for sustainable development cannot be overstated. It is a cornerstone for economic growth, environmental sustainability, and social well-being. As the global community continues to face challenges in achieving the SDGs, the need for robust, adaptable, and forward-looking QI is only becoming more urgent.

I am proud that this publication is the result of UNIDO's successful collaboration with the National Metrology Institute of Germany (PTB). The spirit of solidarity and cooperation guides our efforts, and we look forward to continuing working with our partners to create a sustainable future for all.

GERD MÜLLER

Director General, UNIDO

FOREWORD

Quality infrastructure and legal systems are interrelated in multiple ways and form a robust foundation that allows products, services, and processes to meet established standards and comply with laws and regulations. However, it cannot be taken for granted that the two disciplines will always be coordinated, harmonious and consistent with each other. This publication underlines the need for a close dialogue among QI institutions, legal actors and policy makers. It offers a sound demonstration of best practices and examples from selected sectors.

Measurements, standards and conformity assessment form an essential part of every economic system. Ideally, they operate in such a way that they are seldom noticed. They are also an indispensable instrument in the interaction between international or regional trade partners and local sellers or buyers in everyday transactions. In addition, governments enact laws and regulations to protect public health, safety, and the environment. These laws often refer to specific standards or require that products meet certain criteria. Quality infrastructure provides the technical basis for these regulations and is also needed to develop and adopt new technologies and foster innovation. Quality infrastructure thus acts in a very dynamic environment.

For instance, national metrology institutes ensure the accuracy and reliability of measurements, without which regulations cannot be effectively enforced. PTB, as the national metrology institute of Germany, performs tasks assigned by 25 laws and regulations at a national level alone. This pertains to the implementation of these requirements for approx. 160 European harmonized and nationally regulated measuring devices. In order to ensure these tasks to be fulfilled, PTB staff members actively participate in more than 1.000 boards and committees at a national, European and international level. This allows new developments, trends and requirements to be acknowledged, including those that are the result of digitalization such as the digital calibration certificate (DCC) and the use of artificial intelligence. At the same time, it adequately considers the role and contribution of metrology vis-à-vis other quality infrastructure disciplines and various legal systems.

Quality infrastructure provides the framework for mutual recognition and equivalence agreements. Internationally harmonized standards and accredited conformity assessment services help to reduce technical barriers to trade, providing the technical basis for products certified in one country being accepted in another. In sum, a smooth interaction between quality infrastructure and legal systems ensures that laws and regulations are technically sound and effectively enforced without hampering trade and innovation. This synergy enhances public trust, promotes compliance, facilitates trade, and supports innovation and sustainability.

Developed conjointly by UNIDO and PTB, this document highlights how sustainable and inclusive economic and social development can succeed via an active dialogue among QI experts, legal professionals, policy makers and regulators. Such a collaborative approach is key to exploiting the full potential of quality infrastructure and its services, and allows us to address collectively the grand challenges we are all facing today together worldwide.

CORNELIA DENZ

PTB, President

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December 2024

ACRONYMS AND ABBREVIATIONS

QI	Quality Infrastructure
AB	Accreditation Body
AFRAC	African Accreditation Cooperation
AFRIMETS	Intra-Africa Metrology System
APAC	Asia Pacific Accreditation Cooperation
APMLF	Asia Pacific Legal Metrology Forum
APMP	Asia Pacific Metrology Programme
ARAC	Arab Accreditation Cooperation
ARSO	African Organization for Standardization
ASTA	American Spices Trade Association
BIPM	International Office for Weights and Measures
CA	Conformity Assessment
CAB	Conformity Assessment Bodies
CAC	Codex Alimentarius Commission
CARICOM	Caribbean Community
CARIMET	Caribbean Metrology Cooperation
CC	Consultative Committees
CE	European Conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CEO	Chief Executive Officer
CGPM	General Conference on Weights and Measures
CIPM	International Committee for Weights and Measures
CMC	Calibration and Measurement Capabilities
CoC	Chain of Custody Certification
COO	Country of Origin
COOMET	Euro-Asian Cooperation of National Metrological Institutions
COP	Conformity of Production

COPANT	Pan American Standards Commission
CROSQ	CARICOM Regional Organization for Standards and Quality
CS	Certification System
EA	European co-operation for Accreditation
EEAC	European Economic Area Countries
EFSA	European Food Safety Authority
EPA	United States Environmental Protection Agency
ESA	European Spice Association
EU	European Union
EURAMET	European Association of National Metrology Institutes
FAO	Food and Agriculture Organization
FBO	Food Business Operators
FSC	Forest Stewardship Council
FSMA	Food Safety Modernization Act
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GLP	Good Laboratory Practices
GQN	Global Quality Networks
GRP	Good Regulatory Practice
GSO	Gulf Cooperation Council Standardization Organization
GULFMET	Gulf Association for Metrology
GVC	Global Value Chains
HACCP	Hazard Analysis and Critical Control Points
HC	Health Certificates
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
IATF	International Automotive Task Force
ICATM	International Cooperation on Alternative Test Methods
ICCR	International Cooperation in Cosmetics Regulation
ICONTEC	Colombian Institute of Technical Standards and Certification
IEC	International Electrotechnical Commission
IGQN	International and Global Quality Networks
ILAC	International Laboratory Accreditation Cooperation

INetQI	International Network of Quality Infrastructure
INVIMA	National Institute for Food and Drug Surveillance of Colombia
IOSTA	International Organization of Spice Trade Associations
IPPC	FAO International Plan Protection Convention
ISO	International Organization for Standardization
ISO CASCO	ISO committee for conformity assessment
ITU	International Communications Union
KCDB	Key Comparison Database
KPI	Key Performance Indicators
MAD	Mutual Acceptance Data
MLA	Multilateral Recognition Arrangement
MRA	Mutual Recognition Arrangement
NAB	National Accreditation Body
NGO	Non-Governmental Organization
NHTSA	United States National Highway Traffic Safety Administration
NMI	National Metrology Institute
NQC	National Quality Council
NQI	National Quality Infrastructure
NQP	National Quality Policy
NSB	National Standardization Body
OECD	Organization for Economic Cooperation and Development
WOAH	World Organization for Animal Health
OAS	Organization of American States
OIML	International Organization of Legal Metrology
OIML	International Organization on Legal Metrology
ONAC	Colombian National Accreditation Body
PAH	Polycyclic Aromatic Hydrocarbons
PAQI	Pan African Quality Infrastructure
PASC	Pacific Area Standards Congress
PDO	Protected Designation of Origin
PEFC	Programme for the Endorsement of Forest Certification
PGI	Protected Geographic Indications

PTB	*Physikalisch-Technische Bundesanstalt*
QI	Quality Infrastructure
QICA	Quality Infrastructure Council for the Americas
QP	Quality Policy
RAB	Regional Accreditation Body
RAM	Andean Metrology Network
RIA	Regulatory Impact Assessment
RMO	Regional Metrology Organization
SADCA	Southern African Development Community Cooperation in Accreditation
SADCMET	Southern African Development Community Cooperation in Measurement Traceability
SARSO	South Asian Regional Standards Organization
SDG	Sustainable Development Goals
SDO	Technical Standards Development Organizations
SI	International System of Units
SIC	Superintendency of Industry and Commerce of Colombia
SICAL	National Quality Subsystem
SIM	Inter-American Metrology System
SPS	Sanitary and Phytosanitary Measures
SSI	Sustainable Spices Initiative
TBT	Technical Barriers to Trade
TFA	Trade Facilitation Agreement
UN	United Nations
UNDP	United Nations Development Programme
UNECE	United Nations Economic Commission for Europe
UNIDO	United Nations Industrial Development Organization
US	United States of America
VIM	International Vocabulary of Metrology
VIML	International Vocabulary of Legal Metrology
WHO	World Health Organization
WMO	World Meteorological Organization
WTO	World Trade Organization

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INTRODUCTION

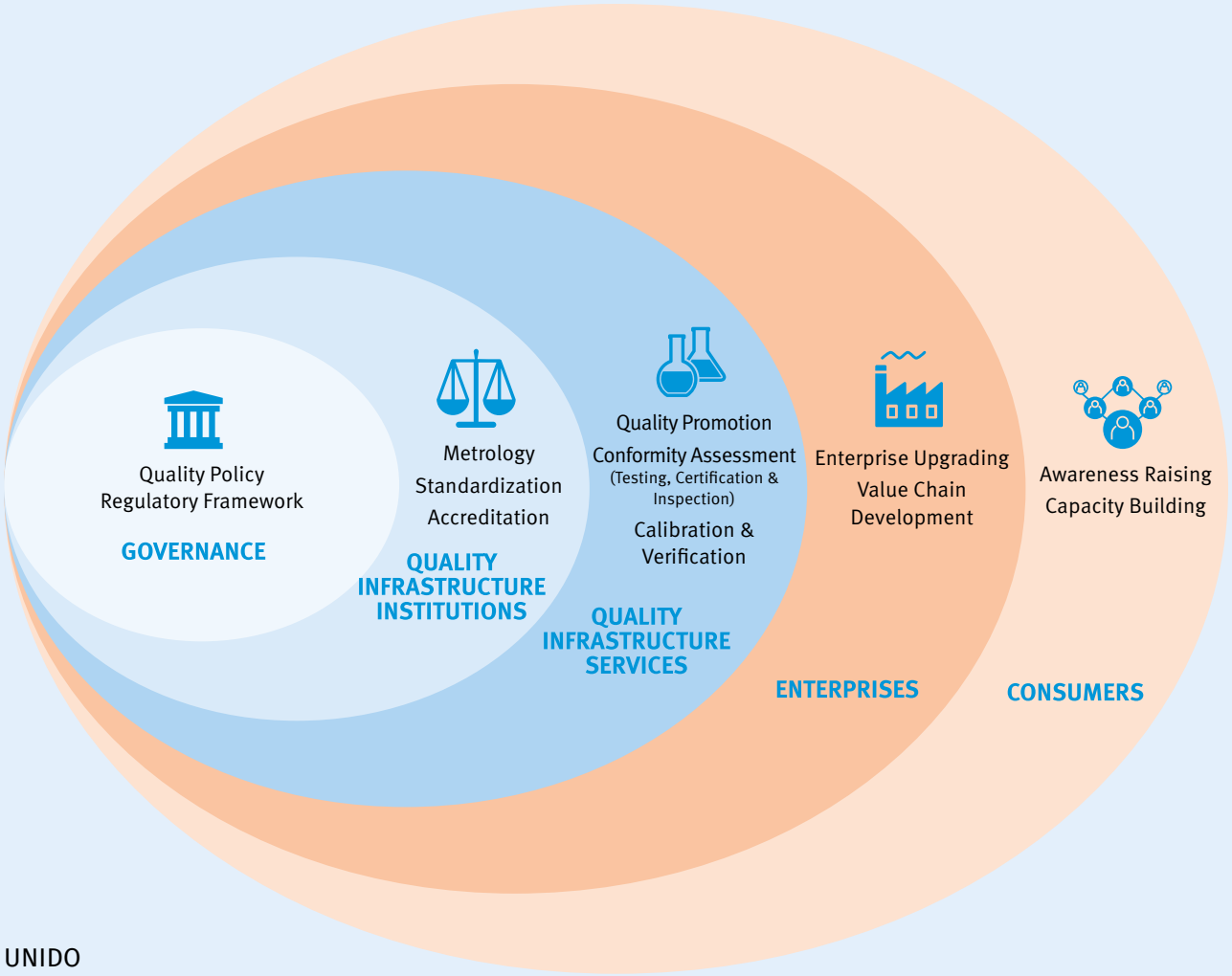
Quality Infrastructure (QI) consists of public and private organizations that provide services in areas such as standardization, accreditation, measurements and conformity assessment for state actors, industry, academia and consumers. QI requires a sound legal framework that provides a foundation for the QI system to operate and to support sectorial policies and regulations by potentiating efficiencies and establishing clear responsibilities and practices. This framework can also provide an overarching structure to reform, consolidate, refine, and maintain effective quality programs in a coordinated manner.

Throughout recent history, QI has been pivotal in shaping the landscape of industry, trade, and technology. The last three decades have marked a significant growth in global trade, subsequently elevating the role of QI. Moreover, more and more countries have acknowledged the role of QI for sustainable development and as a source of support for achieving the Sustainable Development Goals (SDGs). As a result, countries are promoting their own QI, which includes the development of a corresponding legal framework. It can be observed that existing QI legislation, such as standards and metrology laws, is being updated. Elsewhere, new laws are being adopted that cover the whole of QI, the QI pillars, conformity assessment bodies and their interactions. This document serves as a guide for QI operators to engage and maintain dialogue with legal professionals, policymakers, and regulators on QI's potential to support society in general, the economy and the government. To this end, QI must be legally defined and structured in the ways described in this report, as well as planned, administered and utilized by all interested parties in a coordinated manner.

Furthermore, a well-established QI plays a vital role in the transformation of economic activities, social practices, and human behavior. It allows consumers to make informed choices, fosters innovation, encourages business and industry to adopt new technologies and organization methods, and assists public authorities in designing and implementing public policies aligned with the SDGs[1], as well as in complying with international conventions. Moreover, QI aids legislators, policymakers, and regulators in fulfilling their official responsibilities by monitoring the compliance of products and processes and their environmental impact. This facilitates informed decisions that affect the national interest such as the protection of human health and the environment

[1] UNIDO (2020). "Rebooting Quality Infrastructure for a Sustainable Development". Available at: https://hub.unido.org/sites/default/files/publications/QI_SDG_PUBLICATION_Dec2019.pdf

GRAPHIC 1 THE QUALITY INFRASTRUCTURE SYSTEM



UNIDO

However, in some cases, existing and new legal frameworks do not allow QI systems to be fully harmonized with international standards or good practices nor do they allow the QI components to coordinate their development and services in an efficient or effective manner. Some legal frameworks restrict the use of QI and its services for the implementation of public policies and, in particular, technical regulations. Thus, QI legal frameworks sometimes do not ensure that products and services consistently meet rigorous requirements of quality, safety, and reliability, and thus do not adequately consider issues of international trade, such as: harmonization of standards, or mutual recognition of conformity assessment procedures and results.

Therefore, the design of the legal framework is key for ensuring that QI is functional, technically competent, impartial, independent, neutral, and non-discriminatory towards third parties. This serves the three dimensions addressed by the SDGs: building prosperity, meeting the needs of people, and protecting the planet. QI practitioners should then promote the further development and adaptation of the QI legal framework. In addition, legal formalism and other sciences have the potential to differ in their approaches, methods and results.

Therefore, QI practitioners need to develop knowledge to gain perspective into relevant legal issues and be able to understand the legal process. At the same time, legislators, policymakers, legal drafters, regulators and other legal operators need to understand QI development needs so that they can engage in productive interaction and discussion.

This publication delves into the development of the QI legal framework and the relationship of the QI system with sectoral policies and technical regulations. It also highlights the critical role of QI in upholding the quality of products and services, facilitating international trade, and contributing to sustainable development.

The publication addresses various issues that need to be considered before moving on to the specific legal considerations of QI as a system. It begins by introducing non-experts to the definition and basic concepts of QI and legal systems and their main characteristics (Chapter 1). Next, it focuses on the alignment of QI institutions with international bodies and regional integration schemes. In particular, it describes the existing international QI conventions and global QI networks, and their implications for national QI systems (Chapter 2). Afterwards, the report emphasizes that the development of a QI legal framework must be part of a wider process, ideally driven by a quality policy (Chapter 3).

Concrete considerations for preparing QI legislation are presented including the most salient issues and differences among common legal observance and focuses on best practice through a detailed elaboration on specific considerations for the development of coherent legislation for the core QI pillars and their services (Chapter 4). These suggestions are also organized into sections on the different aspects of the QI system: standardization, metrology, accreditation, conformity assessment and calibration services, and legal metrology (Annexes 1 to 5).

Thereafter, the report presents legal considerations for state actors when using QI and sheds light on legal guidelines to ensure support for sectoral policies through QI (Chapter 5). It also provides specific information on key value chains using the examples of wood, food products, automobiles, and cosmetics, and explores sector specific regulation gaps and good practices based on the proper use of QI (Chapter 6).

As we navigate through an era of rapid technological advancement and complex global challenges, QI needs to continue adapting, shaping and being shaped by legal frameworks to meet new demands such as sustainability, digitalization, and global health and safety concerns. This publication is designed to support this process.

It should be noted that this document does not cover all possible current legal practices or settings. Therefore, for certain specific systems and regions, further analysis is advised when drafting QI legislation.

Developed by PTB and UNIDO, this document aims to foster a comprehensive understanding of how QI operates, emphasizing its significance in the global economy. We hope it encourages meaningful discussions among QI experts, legal professionals, policy makers, and regulators on their roles in shaping policies, legal frameworks, and practices. These collaborative efforts are essential for leveraging QI and its services in order to address diverse challenges, trends, and governmental needs effectively and efficiently.

1

AN OVERVIEW OF QUALITY INFRASTRUCTURE AND LEGAL SYSTEMS

This document brings two concepts and communities together: Quality Infrastructure and legal systems. This chapter introduces and presents a general understanding of these topics.

1.1.

A BRIEF INTRODUCTION TO QUALITY INFRASTRUCTURE

The International Network of Quality Infrastructure (INetQI) has defined Quality Infrastructure (QI) as:

"...the system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services, and processes. The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment, and market surveillance."[2]

Building on the above background, QI is a system that provides a technical basis to ensure the quality of materials, products, processes, companies, personnel, and quality in science, in current and new technologies, in infrastructure, in natural resources, in our environment, and in our lives.

It should be noted, however, that the legal frameworks for market surveillance are not addressed specifically in this document[3], but for interaction with core QI, some examples are provided in Chapter 6, "QI and legal aspects of technical regulation framework: sector examples and specifications".

THE CORE QI AND THE THREE QI PILLARS

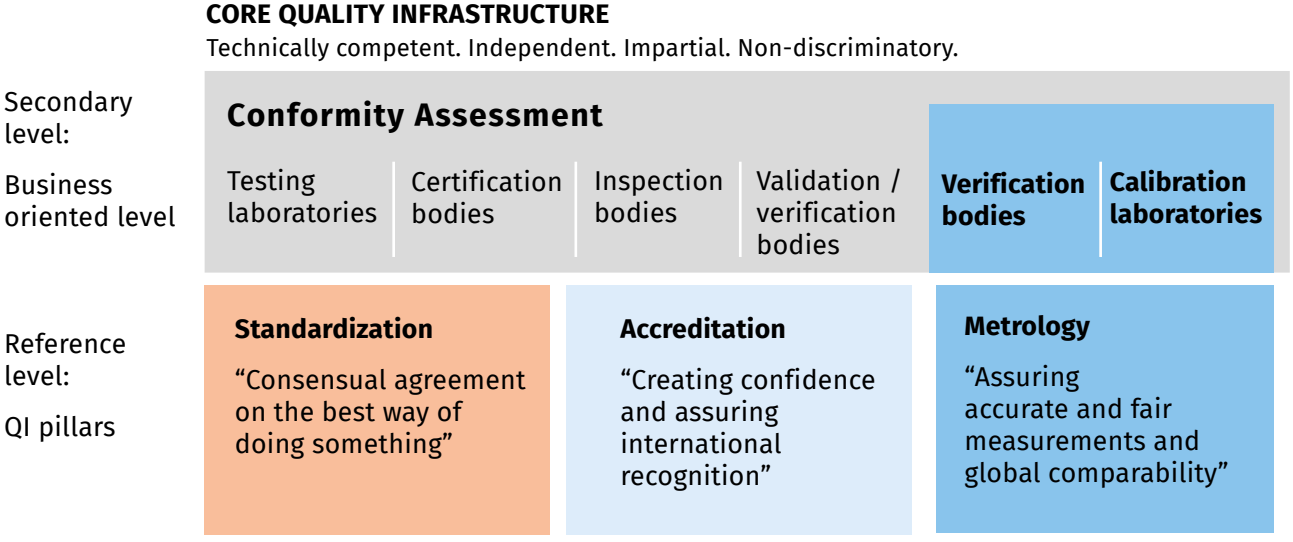
A technical basis is provided mainly by the core QI, which is structured hierarchically and consists of a reference level (standardization, accreditation and metrology) and a secondary level (conformity assessment). The organizations providing core QI competence and services may be public or private in nature but need to ensure the following requirements: technical competence, impartiality, independence, neutrality, and non-discrimination towards third parties.

The reference level is normally covered by three main QI pillars and its institutions: the national standardization body (NSB), the national accreditation body (NAB) and the national metrology institute (NMI). These institutions interact and are the countries' link to the international QI community for comparability, traceability, harmonization, recognition, and knowledge management. In some countries, some of the national QI pillar institutions may not exist. However, the reference level may be covered, for example, by a regionally organized QI pillar institution.

[2] INETQI (2017). QI definition. Available at: https://www.inetqi.net/documentation/quality-infrastructure-definition/

[3] On market surveillance, see for example PTB-MERCOSUR (2023) Madriñán, Ramón (Ed.) Good Practices Guide for Market Surveillance of Mercosur Energy Efficiency Labeling Authorities. (Spanish) Available at: https://www.mercosur.int/wp-content/uploads/2023/12/GUÍA-DE-BUENAS-PRÁCTICAS-Projeto-de-Cooperacao-MERCOSUL-PTB.pdf

GRAPHIC 2 THE CORE QUALITY INFRASTRUCTURE



PTB[4]

[4] PTB, based on the work of Alexis Valqui, international expert in Quality Infrastructure.

The secondary level is covered by calibration laboratories and conformity assessment bodies that perform services that include testing, certification, inspection, verification, and validation. These laboratories and bodies act in most cases as demand driven organizations in a competitive environment. Accreditation is a recognized instrument to ensure that these market agents also fulfill the requirements mentioned above.

In the following section, a concise explanation of the core components of QI and its logic is presented:

STANDARDIZATION: CONSENSUAL AGREEMENT ON THE BEST WAY OF DOING SOMETHING

The development of technical standards follows a structured and consensus-driven process that involves active collaboration between stakeholders, with input from experts in the relevant field of focus for each technical standard. Through this process, stakeholders agree on the best way of doing something: Standardization takes place in technical committees organized by national standardization bodies as well as in regional and international standards organizations. The result of the standardization process is technical standards, which are technical documents that outline agreed upon specifications, criteria and guidelines on the design, use and performance of materials, products, processes, services, systems and individuals. Regional and international harmonization of technical standards is achieved through corresponding standards organizations.

CONFORMITY ASSESSMENT

The process of conformity assessment demonstrates whether a material, product, service, personnel qualification, management system, claim, or piece of measurement equipment complies with defined technical standards and specified requirements[5]. Conformity assessment services are provided by conformity assessment bodies (CABs). These processes are implemented following applicable ISO CASCO technical standards, and the services may be accredited. Undergoing the conformity assessment process, which may be "voluntary" (contractually required) or mandatory (required by primary or secondary legislation), has the benefit of providing consumers and other stakeholders with added confidence.[6]

METROLOGY: ASSURING ACCURATE MEASUREMENTS AND GLOBAL COMPARABILITY

To be able to demonstrate the fulfillment of quality requirements through conformity assessment, accurate measurements are needed, and global comparability is a must. This is achieved through a network of interconnected measurement traceability chains to the International System of Units (SI) provided through national, regional and international metrology systems. Metrology is the science of measurement and its application, and includes both theoretical and practical aspects, regardless of the measurement uncertainty or the field of application.[7]

ACCREDITATION: CREATING CONFIDENCE AND ASSURING INTERNATIONAL RECOGNITION

An "umbrella" of confidence is needed to ensure the recognition of conformity assessment services provided by the CAB, including international recognition. Accreditation is the formal attestation or statement by an independent third party, commonly known as an accreditation body (AB), that a conformity assessment body, (e.g., a certification, validation and verification or inspection body, or a testing, medical or calibration laboratory), is competent to conduct a specific conformity assessment service. ABs may be established locally or, in some instances regionally, considering impeding needs and possibilities.

5 ISO (2024), Conformity assessment definition. Available at: https://www.iso.org/cms/%20render/live/en/sites/isoorg/home/standards/committee-for-conformity-assessm.html#:~:text=The%20process%20of%20conformity%20assessment%20demonstrates%20whether%20a,standards%2C%20regulations%2C%20contracts%2C%20programmes%2C%20or%20other%20normative%20documents.

6 PTB and WB (2019): Quality Infrastructure Rapid Diagnostic Toolkit. Available at: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/docs/QI_Toolkit/PTB_Info_QI_Rapid_Diagnostic_Tool_User_Guide_EN.pdf

7 BIPM (2021): National Metrology Systems Developing the institutional and legislative framework. Available at: https://www.bipm.org/documents/20126/42177518/National-Metrology-Systems.pdf/3f13d88c-aef6-9c50-62dc-39fa6f48f6e9

QI COORDINATION: CREATING A UNIFIED QI SYSTEM.

Standardization, metrology, and accreditation, as well as related conformity assessment services, are not isolated components within a national or regional quality infrastructure. On the contrary, the QI pillars play a central and practical role in various aspects of the QI.

Therefore, there is also a demand for active coordination between the NSB, NMI, and NAB to foster a unified basis for calibration and conformity assessment activities within the QI (we may refer to this as "centralized QI coordination").

To continue, some specific aspects of QI are addressed:

QI PILLARS AS "PUBLIC GOODS"

In economics, public goods must fulfill two main characteristics: being non-excludable and being non-rivalrous. Additionally, its use by one actor does not prevent access by other actors, nor does it reduce availability for other actors.[8] In general, the provision of public goods is part of governmental activities.

The network of interconnected measurement traceability chains to the International System of Units (SI), which is provided through national, regional and international metrology systems, is non-rivalrous and in principle non-excludable. However, fees are charged for the calibration needed to connect to these traceability chains. The "umbrella of confidence" that accreditation provides, which covers conformity assessment and thus also products, is non-rivalrous and in principle non-excludable, but extremely high accreditation fees could weaken its character as a public good character. Access to the variety of technical standards developed through a consensus-driven process in which stakeholders collaborate actively on a national, regional and international basis is non-rivalrous and in principle non-excludable. However, for some actors, the cost to access certain technical standards may be prohibitive. Given the importance of QI for sustainable development, various mechanisms are being implemented to better ensure the non-excludable criteria of QI are fulfilled, though fulfilling these criteria remains a challenge. The answer to the original question is that the greater the extent to which the QI pillars can serve as a public good, the more QI can unfold its positive sustainable development effects.

In conclusion, the three QI pillars must be seen as a quasi-public good, requiring the state in order to ensure their establishment, functioning and accessibility, even when part of the competence and services are provided through privately organized entities.

[8] Oakland, W. H. (1987). "Theory of public goods. In Handbook of public economics" (Vol. 2, pp. 485–535). Elsevier.

NATIONAL QI AND ITS REGIONAL AND INTERNATIONAL EMBEDDING

The national QI pillars (standardization, accreditation and metrology) are embedded in regional and international QI organizations and networks to collaborate on and realize regional and international harmonization, metrological traceability and comparability and confidence, and mutual recognition. See Table 1 - international and regional QI organizations.

TABLE 1 INTERNATIONAL AND REGIONAL QI ORGANIZATIONS (REGIONAL ORGANIZATIONS HERE ARE LIMITED TO THOSE ORGANIZED UNDER THE INTERNATIONAL QI ORGANIZATIONS)

STANDARDIZATION	ACCREDITATION	METROLOGY
INTERNATIONAL ORGANIZATION		
International Organization for Standardization (ISO) International Electrotechnical Commission (IEC)	International Laboratory Accreditation Cooperation (ILAC) International Accreditation Forum (IAF)[9]	International Office for Weights and Measures (BIPM) International Organization of Legal Metrology (OIML)
REGIONAL ORGANIZATIONS		
Special agreements (ISO/IEC)	*Recognized Regional Cooperation Bodies (ILAC) / Regional Accreditation Groups (IAF)*	*Regional Metrology Organizations (BIPM)*
ARSO: African Organization for Standardization AFSEC: African Electrotechnical Standardization Committee CEN: European Committee for Standardization CENELEC: European Committee for Electrotechnical Standardization COPANT: Pan American Standards Commission GSO: Gulf Cooperation Council Standardization Organization PASC: Pacific Area Standards Congress SARSO: South Asian Regional Standards Organization	AFRAC: African Accreditation Cooperation APAC: Asia Pacific Accreditation Cooperation ARAC: Arab Accreditation Cooperation IAAC: Inter American Accreditation Cooperation EA: European co-operation for Accreditation SADCA: Southern African Development Community Cooperation in Accreditation	AFRIMETS: Intra-Africa Metrology System APMLF: Asia Pacific Legal Metrology Forum APMP: Asia Pacific Metrology Programme COOMET: Euro-Asian Cooperation of National Metrological Institutions EURAMET: European Association of National Metrology Institutes GULFMET: Gulf Association for Metrology SIM: Inter-American Metrology System

THE DIVERSITY OF QI USERS

Users of the core QI and its services include manufacturers, industry, service providers, traders, the science, technology and innovation ecosystem, consumers, and the state as a policy maker, regulator, buyer of products and services, and public service providers.

These users need legally stable and reliable QI and services to:

a) Define quality and safety requirements of goods, services, and processes.

b) Meet and demonstrate the fulfillment of these requirements.

c) Control and monitor compliance with these requirements (e.g. market surveillance).

d) Increase the productivity, efficiency and effectiveness of their processes and interactions.

e) Facilitate, take part in and sustain fair domestic and international trade.

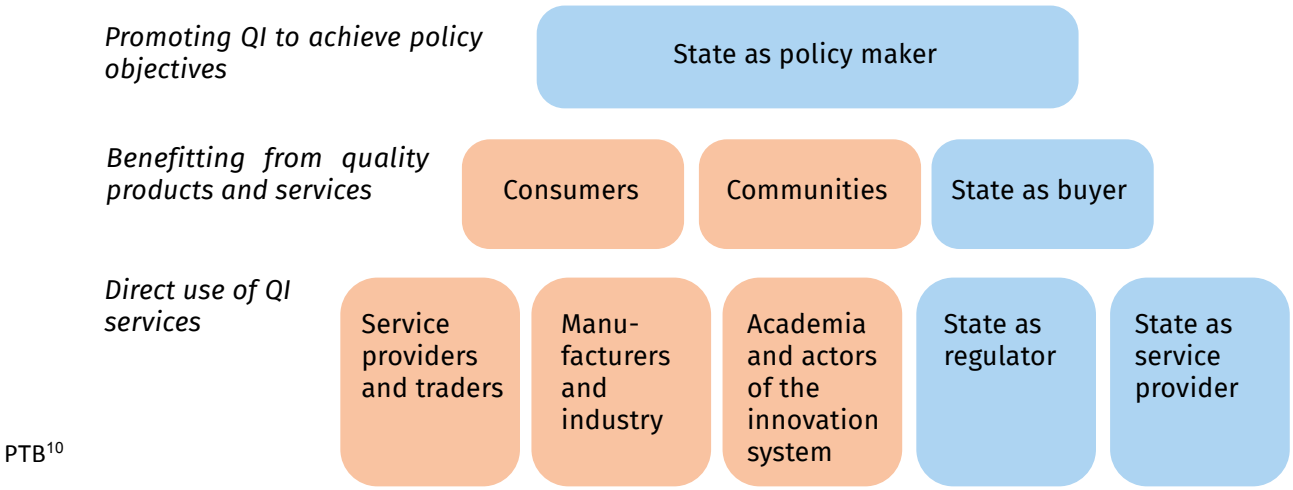
f) Monitor the quantity and quality of materials and resources and their efficient use.

g) Develop new goods, services and processes and foster innovation.

h) Have a technical foundation for scientific and technological development and technology transfer, and produce findable, accessible, interoperable, reusable and comparable data and information.

9 In future, ILAC and IAF will be merge into “GLOBAC”

GRAPHIC 3 THE USERS OF QI



PTB[10]

In other words, the core QI must operate within and for the benefit of productive, service oriented, regulated, development oriented, scientific, monitoring, and innovative environments. It serves the interests of a range of public and private users who have diverse purposes. Focusing QI on only one purpose in detriment to the others must be avoided.

Some users of the core QI can develop their own infrastructure (private standards, laboratories, inspectors, etc.) in order to expand the QI to include their own needs. This user infrastructure is not seen as part of the core QI until it fulfills all the requirements listed above.

DOES A BLUEPRINT EXIST FOR THE QI SCOPE OF A COUNTRY?[11]

While there are international standards for the requirements that a national QI needs to fulfill, there is not a blueprint for the scope of a national QI that is valid for all types of countries.

For example, when addressing the quality of products, the in-country QI needed will defer if the corresponding products are being imported, are being produced in-country, or are even being exported. In a fully importing situation, the QI is needed in order to demonstrate that the products comply with the expected quality criteria. In this case, a well performed acceptance of foreign conformity assessment results could be sufficient. Depending on the risks and the resources, it could make sense to install some QI in-country services or to use regional existing capacities to strengthen the required in-situ conformity assessment.

In an in-country production situation, the QI is needed not only to demonstrate that the products comply with the expected quality criteria, but also to develop and innovate products and to ensure that companies are competitive and that production processes yield quality products. The required QI in an in-country production situation needs a wider scope than in a solely import situation.

Although it is possible to export raw material with no QI or a weak QI, one must then accept low bulk prices and only being able to estimate the exporting volumes. Any value added, starting from evaluating the quality of the raw material to be exported and the first processing steps of the raw material, requires a functioning QI. This applies to an even greater extent if products destined for international markets are to be competitive. Therefore, the scope of the required QI also depends on the degree of industrialization and diversification present in a given economy.

In some situations, countries can justify accessing QI services from neighboring countries or building regional cooperation structures to ensure the provision of QI services in their countries. An example of the latter is the National Accreditation Focal Points in smaller economies accessed by fully functioning Accreditation Bodies in the region. Potential problems include dependency created by such regional solutions and an insufficiency of the service provided to cover all the QI needs. Therefore, a continuous evaluation of optimal solutions is required.

In conclusion, there is no blueprint for the optimal scope of the QI of a country.

[10] PTB, based on the work of Alexis Valqui, international expert in Quality Infrastructure.

[11] See PTB, OAS and SIM (2007) Sanetra, Clemens and Marbán, Rocío M., A National Quality Infrastructure.

Finally, QI plays a significant role in advancing three dimensions addressed by the Sustainable Development Goals (SDGs):

- Building prosperity (economic dimension)
- Meeting the needs of people (social dimension)
- Protecting the planet (environmental dimension)

Creating an overview with these three dimensions shows the interdependence of the various goals, targets, and approaches and underscores the importance of an integrated implementation. QI encourages the use of consensus-based technical standards, which strengthens international cooperation and partnerships.

Supporting the SDGs and measuring progress in achieving specific targets requires a robust QI.[12] The following subsections present examples of how QI supports new challenges and megatrends related to these three dimensions of sustainability:

ECONOMIC MEGATRENDS AND QI

QI supports effective domestic markets, eases access to foreign markets, and helps to promote sustainable economic development. The economic success and prosperity of nations is inextricably linked to their ability to efficiently manufacture and trade fit-for-purpose and tested products and components that are accepted by trading partners and meet destination market and consumer requirements. Therefore, manufacturers need to ensure that their products are of consistent quality, follow relevant technical regulations and technical standards, and meet necessary requirements and specifications.

A robust and effective QI is indispensable for meeting the requirements of target markets and harnessing the power of trade, while effectively addressing social and environmental aspects without creating unnecessary barriers to international trade. For example, when sustained by an appropriate legal framework, QI provides valuable and critical support to governments and organizations as they seek to enhance energy efficiency, economic performance, and the transition to clean energy, while preventing unsafe, unhealthy, or environmentally harmful products from entering the marketplace.

Furthermore, consensus-based technical standards, metrology and conformity assessment capabilities make vital contributions to foster innovation by promoting the development and adoption of innovative technologies and products in line with internationally established practices.[13]

ENVIRONMENTAL MEGATRENDS AND QI

QI plays a key role in protecting the planet and its biosphere by aiding in the responsible consumption of scarce resources and the mitigation of climate change effects. Additionally, QI institutions and services are essential in facilitating the transition towards sustainable production and consumption patterns by providing accurate information about the materials, energy, water, and land used, as well as emissions and waste. This information is vital for developing and implementing sustainability policies, and for encouraging eco-friendly behavior among key concerned parties.[14]

Accredited certification schemes that support sustainable procurement, such as environmental or socially responsible labels, are increasingly being sought after by purchasing authorities and used by bidders as a way of determining their environmental or social performance.

In addition, conformity assessment bodies (CABs) are critical in bringing confidence to consumers and enabling market surveillance authorities to verify that products and processes adhere to technical standards and technical regulations. Through testing, certification, and inspection, CABs ensure that materials and waste are within regulatory limits. For example, testing provides evidence that water is demonstrably safe for consumption, controls pollution, and ensures that potable water can reach more people.

Accurate measurements are central to understanding climate change. Having reliable data to monitor essential climate variables is key to comprehending and monitoring atmospheric, oceanic, and terrestrial changes in order to find solutions. Metrology is key to ensuring the quality of this data by providing measurements that are fully traceable, stable over time and that have low uncertainty. It supports the provision of information related to the use of materials, energy, and water, enabling producers to quantify and record the emissions and waste generated during material extraction, production processes and product use.

Moreover, metrological services support the development of reliable and internationally

[12] ISO (2023), Standards and public policy: A toolkit for national standards bodies. Available at: https://www.iso.org/publication/PUB100476.html

[13] UNIDO (2019). Quality Infrastructure for Sustainable Development. Available at: https://hub.unido.org/sites/default/files/publications/QI%20and%20Sustainable%20Development_2019.PDF

[14] UNIDO (2020). Rebooting Quality Infrastructure for a Sustainable Development. Available at: https://hub.unido.org/sites/default/files/publications/QI_SDG_PUBLICATION_Dec2019.pdf

comparable metrics for water conservation – for example, by providing measurements of the water footprint, or volume of freshwater used, of products and activities. Thanks to metrology, meters can also be calibrated that guarantee conservation and sustainable use and consumption, and therefore promote water efficiency.[15]

National QI institutions, along with their regional and international collaboration networks, are indispensable in transforming production and consumption patterns, leading to a better quality of life, substantial reductions in the ecological footprints of human economic activities such as environmental pollution and the consumption of raw materials and energy.[16]

Likewise, QI institutions and services provide an essential contribution to implementing policies and actions that aim to achieve the sustainable use of marine resources (life below water) and the protection of on land ecosystems (life on land). This includes measurement capabilities, dissemination of good practices, support for management, and monitoring, reporting and verification of compliance.[17]

SOCIAL "MEGATRENDS" AND QI

QI ensures that people's needs are met and plays a key role in ensuring food security and safety, sustainable agriculture, good health and well-being, among other areas. For instance, QI institutions and services have a fundamental role in the trading of food and agricultural products by showing that they are fit and safe. It also contributes to the achievement of key SDG targets to end hunger, food insecurity and malnutrition in all its forms, and to access safe, nutritious, and sufficient food for all. It thereby ensures that food is grown in a sustainable way.[18] Furthermore, QI development should consider gender as a cross-cutting theme at all stages of the process, including the development of quality related policies, legislation, technical standards and regulations in order to prevent gender inequalities from being perpetuated. For example, the development of gender-sensitive technical standards and regulations can aid the drive for gender equality by ensuring that gender-related topics are given sufficient consideration.[19]

In agribusiness, market-driven technical standards, mandatory technical regulations, and related compliance procedures address aspects such as guidance on agricultural practices, requirements, and technical standards for agricultural equipment, seeds, plants, animal feeds and other key agricultural inputs such as fertilizers and pesticides. The correct application of these technical standards and regulations allows people to live healthy lives and improve their social and economic wellbeing.

Accredited test results, inspection data and accreditation certificates let consumers, suppliers, and purchasers have confidence in the quality and safety of goods and in the provision of services throughout the supply chain. Samples, products, services, management systems and personnel can be evaluated against specified requirements by accredited laboratories and inspection and certification bodies, to ensure that they are fit-for-purpose and safe for consumption. In addition, chemical metrology provides essential inputs for addressing food safety issues such as tracing contaminants in food and foodstuffs.

QI is equally important in the health sector, which depends on inputs from medical devices, processes, and activities. Quality in healthcare relies on correct dosages of medicines and on precision in physical and chemical processes and activities, as well as in biological measurements used to diagnose health conditions and ensure that therapies are safe and effective. Accurate measurements improve patient outcomes, save time, and reduce costs.[20]

QI is of high relevance for the development of vaccines through related scientific testing methods that rely on precise measurements. Such vaccines play a key role in public health and their production and distribution are highly regulated and must therefore comply with technical requirements to ensure quality. Furthermore, guidelines and regulations used to verify the compliance of medical devices and methods can only be relied on if the measurements and processes involved are accurate, traceable to internationally agreed reference technical standards, and performed using competently calibrated instruments.

Similarly, technical standardization and technical regulations help to ensure that medical devices are safe and fit-for-purpose. In this way, inferior products are prevented from entering the market. Medicines and other major inputs to healthcare systems must also meet stringent quality and safety requirements, most of which are covered by the World Health Organization (WHO)'s technical standards, regulations, guidelines, and quality assurance procedures.[21]

[15] Idem
[16] UNIDO (2019). Quality Infrastructure for Sustainable Development. Available at: https://hub.unido.org/sites/default/files/publications/QI%20and%20Sustainable%20Development_2019.PDF
[17] Idem
[18] Idem
[19] Idem
[20] UNIDO, BIPM and OIML (2016). The role of Metrology in the Context of the 2030 Sustainable Development Goals. Available at: https://www.unido.org/sites/default/files/files/2020-08/The_role_of_Metrology_in_the_context_of_SDGs.pdf
[21] UNIDO (2020). Rebooting Quality Infrastructure for a Sustainable Development. Available at: https://hub.unido.org/sites/default/files/publications/QI_SDG_PUBLICATION_Dec2019.pdf

1.2.
A BRIEF INTRODUCTION TO LAW AND LEGAL FRAMEWORKS

Law is understood differently depending on times, places and institutional regimes. Even in one state and at the same moment, the word can have different meanings.[22] In general, the term "law" is referred to all the rules, usually enacted by a government, that are used to order the way in which a society behaves.[23]

The tasks performed by legal practitioners can be broadly categorized as: (i) the preparation of legal rules (e.g. the enactment of legislation by a parliament, also known in the legal profession as "*prescriptive law*"); and (ii) the application and adjudication of the law by lawyers and judges (also known as the interpretation of the law or "*positive law*"). This document deals only with prescriptive legal issues related to the establishment of legal frameworks for QI. However, when drafting legal texts, it is recommended to consider how the legal texts will be read and construed in practice.

By the same line of thought, it should be considered that, for the purposes of this document, legislation is defined as a general and impersonal rule of law initiated by the parliament or government. This is enacted via a previously established process sanctioned (or adopted) and promulgated by executive authorities before being published by them. As such, legislation belongs to the hierarchy of norms that fall under a country's constitution.[24]

The following are some relevant concepts and elements to understand how the law works.

1.2.1.
UNDERSTANDING HIERARCHY IN LEGAL SYSTEMS

Legal systems are by nature hierarchical, with primary and secondary legislation required in order to adhere to constitutional provisions, and individual acts and rulings required in order to ensure that the applicable constitutional provisions and legislation are followed.

Depending on the applicable constitutional provisions in a given country, certain matters such as offenses, penalties, applicable procedures, legal units of measurement, restrictions for regulators and the creation of public entities are normally reserved for primary legislation in a constitutional provision or an act. Parliament may determine which legal issues beyond those indicated above may be determined or regulated by the government.

1.2.2.
TERRITORIAL APPLICATION OF THE LAW

The enactment and application of the law and the adjudication of legal rights is one of the powers of any modern sovereign state. As local law is generally bound to this state power, the application of the law is customarily limited to the country's territory.

National laws are normally applicable in the entirety of the country's territory. However, some laws may apply only to the sub-national level of the state, to municipalities or to other specially designated territories within the state.

As sovereign states, countries also have the power to sign treaties and conventions with other countries that cover a wide range of issues. They may also follow international customs. This external relationship of the states is known as "international law".

In addition, globalization has led to the development of new sources of international law.[25] Traditionally, as indicated above, international law has been based on treaties and customary practices. However, new sources of law prepared by global technical networks have emerged that influence international law, forming what can be broadly referred to as "global law" (Teubner, 1997) [26]. In other words, "global law", as an extension of international law, is produced in self-organized processes in which law is structurally coupled with ongoing globalized processes of a highly specialized and technical nature.[27]

As will be explained below, some of these networks are administered within transnational bodies such as UNECE, but this is not always the case. In some instances, these networks operate as scientific or technical associations or even as informal groups of experts. However, whatever their legal nature, they serve similar practical purposes.

Like other transnational legal disciplines, such as accounting or corporate law, QI operates within a series of networks. Technical standardization and professional self-regulation related to quality have moved towards worldwide coordination with

[22] Delperee, Francis (2016): THE MEANING OF THE LAW, Rada for Europe, EU- UNDP Project. Kiev. P. 3
[23] See Cambridge dictionary, https://dictionary.cambridge.org/dictionary/english/law
[24] Delperee, Francis (2016): THE MEANING OF THE LAW, Rada for Europe, EU- UNDP Project. Kiev. P. 3
[25] Gunter Teubner (ED) (1997). Global Law Without a State. England, Ashgate, P.4.
[26] Idem.
[27] Idem.

relative freedom. These technical networks have created (in legal terms) their own boundaries, sources of law, independence, and a unified legal system.[28] They are referred to as "global quality networks" or "GQNs" and include organizations such as ILAC, IAF, ISO and IEC, which also operate through regional networks.

Section 1.3.3 below presents the relationship of QI with international treaties and conventions. It also explains the entities that operate at the international level to form international and global quality networks (GQNs and IGQNs).

1.2.3.

DIFFERENT HISTORICAL LEGAL SYSTEMS

Law is also a product of history. The different legal systems throughout the world are the result of the long historical and cultural processes that have taken place in their respective countries. However, each country has its own legal specificities; in the legal literature, some countries have been clustered as they share some commonalities in their legal culture and history.

Commonwealth countries follow the United Kingdom's common law system, as do its former colonies such as the United States of America. Common law is generally uncodified. This means that there is no comprehensive compilation of legal rules and statutes. While common law does rely on various statutes created by legislative decision, it is largely based on precedent, meaning judicial decisions already made in similar cases. These precedents are maintained over time through the records of the courts as well as historically documented in collections of case law known as yearbooks and reports. Common law functions as an adversarial system, a contest between two opposing parties before a judge who moderates. A jury of ordinary people without legal training decides on the facts of the case. The judge then determines the appropriate sentence based on the jury's verdict. The precedents to be applied in the decision of each new case are determined by the presiding judge. As a result, judges have an enormous role in shaping common law.[29]

Continental Europe and their former colonies follow one form or another of the Napoleonic Civil Code. These states are referred as "civil law" countries. Civil law, in contrast to common law, is codified. Countries with civil law systems have comprehensive, continuously updated legal codes that specify all matters capable of being brought before a court, the applicable procedure, and the appropriate punishment for each offense. Such codes distinguish between three different categories of law: substantive law establishes which acts are subject to criminal or civil prosecution; procedural law establishes how to determine whether a particular action constitutes a criminal act; and criminal law establishes the appropriate penalty. In a civil law system, the judge's role is to establish the facts of the case and to apply the provisions of the applicable code. Though the judge often brings the formal charges, investigates the matter, and decides on the case, he or she works within a framework established by a comprehensive, codified set of laws. The shaping of civil law is generally more dependent on legislative decisions and the work of legal scholars who draft and interpret the codes; however, judicial precedents play a role in interpreting the codes and other legislation.[30]

It should be noted that, in some federal countries, the provinces within the country might not always have the same legal systems. For example, in the US and Canada (two common law countries), the State of Louisiana and the Province of Quebec practice Civil law. Some countries such as Scotland and Israel structure their legal practice as a combination of common law and civil law.

Other historical legal systems are equally as rich and complex as the ones presented above. To mention some relevant examples, Muslim countries follow Sharia law, a body of law that forms part of the Islamic tradition based on the texts of the Quran and on hadith. Another example that should be mentioned is the existence of indigenous legal systems, which are constitutionally recognized in some states.

Furthermore, some legal systems such as that in the United States tilt towards legal realism, where legal issues are confronted vis-à-vis the facts and potential issues of a case, while others tend towards legal formalism. This is the case in certain Latin American countries, where legal cases are to be decided by applying the uncontroversial principles established by the legal system to the facts.

1.2.4.

LAW APPLIES TO FUTURE SITUATIONS

With some exceptions, depending on the type of legal systems, the law only applies to future situations or cases. This means that new legislation or legally binding precedent does not apply to past situations, which in turn entails the law not being retroactive. In some cases, past situations may

28 Gunter Teubner (ED) (1997). Global Law Without a State. England, Ashgate, P.4.

29 Berkeley Law School. The Common Law and Civil Law Traditions. Available at: https://www.law.berkeley.edu/research/the-robbins-collection/exhibitions/common-law-civil-law-traditions/

30 Idem

continue to be governed by the applicable law of the time (retrospectivity), which is the case (for example) with criminal procedure, contracts, and evidence, in which the governing laws of the time are still valid in the future. However, in some cases such as regulations, new laws may indicate how past situations may transition to new legislation.

1.2.5.

THE PUBLIC / PRIVATE LAW DICHOTOMY

It should be noted that, historically, legal scholars have divided the law into private law and public law. In general, private law covers contracts, torts, family, estates, and companies. Public law covers constitutional law, administrative law, and criminal law. This distinction is more prevalent in civil law countries than in common law countries. However, the legal reason for which one or the other is used is different. Also, public law domains require the use of primary or secondary legislation, while contracts, by-laws and powers-of-attorney are the legal forms generally used in private law.

On some occasions, private bodies may be tasked with the administration of some public goods or services or may be public-private initiatives (or mixed bodies). In these cases, legislation dealing with these types of arrangements may need to be specific in several areas in order to clearly identify when public reasoning will apply and when that body may act as a private entity.

1.2.6.

LEGAL CHALLENGES RELATED TO DIGITALIZATION

With the advent of innovative technologies shaping the Fourth Industrial Revolution (4IR), QI is becoming even more relevant. Standardization, for instance, is crucial in promoting the widespread adoption of emerging technologies, ensuring the use of new devices, enhancing interoperability, and establishing clear and common requirements for sustainability, risk mitigation and cybersecurity.

However, new challenges for QI have emerged, particularly regarding testing and certification for intangible or constantly changing products such as machine learning and artificial intelligence (AI) applications. These areas require the use of modern technologies and techniques as well as innovative thinking. The lack of legal frameworks, standardization, metrology, conformity assessment, and inspection services in these domains can hinder the ability of nations to develop and protect their citizens. Therefore, policymakers need to be aware of these rapid changes to be prepared to regulate, thus deriving inclusive benefits from innovative technologies. QI mainly produces data and information that needs to comply with existing rules and regulations for data and information protection and security without limiting the use of this data and information for the original quality purposes.

Governance rules and regulatory approaches for modern technologies need to be agile, flexible, and resilient. This can be achieved through the development of experimental regulations such as regulatory “sandboxes”, anticipatory approaches, multi-stakeholder use of guidelines and technical standards, and the promotion of international initiatives.[31]

[31] UNIDO (2021). Standards & Digital Transformation – Good Governance in a Digital Age. Available at: https://hub.unido.org/sites/default/files/publications/Standard_digital_transformation_2021_ONLINE_0.pdf

2

QI'S RELATIONSHIP WITH INTERNATIONAL LAW AND INSTITUTIONS

QI systems worldwide have evolved to address technical and practical challenges. QI plays a significant role in regional and global trade, particularly in the context of international agreements, such as the World Trade Organization's (WTO) Trade Facilitation Agreement (TFA), Technical Barriers to Trade Agreement (TBT), and Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).

These QI systems have gradually converged, with common measurement units defined by the International System of Units (SI) and mutually acceptable rules for accreditation and conformity acceptance procedures, fostered worldwide by IAF and ILAC.[32] Additionally, standardization bodies work on internationally acceptable technical standards.

While international institutions initially led these efforts, global and regional practices that influence QI activities have emerged.

Alongside GQNs, there are International Quality Networks such as the Metre Convention, the International Organization on Legal Metrology (OIML), the International Communications Union (ITU), the United Nations Economic Commission for Europe (UNECE), the Technical Working Group of the Basel Convention and many others, referred to collectively as international and global quality networks (IGQNs).

Furthermore, several international treaties and conventions require QI to function or provide special rules and schemes for IGQNs. Such is the case of Working Party 29 of UNECE, which provides special mutual acceptance schemes for the local approval of imported vehicles and their spare parts.

It is crucial for QI legislation to consider and incorporate the rules of GQN institutions and other IGQN international bodies to ensure QI institutions' international recognition and the benefits derived from these arrangements.

2.1. INTERNATIONAL QI RELATED CONVENTIONS

IGQNs operate under traditional international laws, as is the case for the Metre Convention and the OIML Convention.

[32] BIPM. The International Systems of Units. Available at: https://www.bipm.org/en/measurement-units

2.1.1. THE METRE CONVENTION

The Metre Convention (Convention du Mètre), signed in Paris on 20 May 1875 by representatives of seventeen nations, was slightly revised in 1921 to expand the scope and responsibilities of the *Bureau international des poids et mesures* (BIPM).[33] Currently, there are more than 60 Member States (states Parties) to the Metre Convention and more than 30 Associate States and Economies (Associates) of the General Conference on Weights and Measures (CGPM).

The Metre Convention is the international treaty that forms the basis for an international agreement on units of measurement. It established the BIPM and defines its funding and management mechanisms. Additionally, it creates a permanent organizational structure for member governments to act in common accord on all matters relating to the international definitions of the units of measurement.[34]

The International Committee for Weights and Measures (CIPM) organizes technical work via its Consultative Committees (CCs), which are charged with planning and executing key comparisons and affirming the validity of the results within the framework of the CIPM mutual recognition agreement (CIPM MRA). This mutual recognition agreement provides the framework within which national metrology institutes (NMIs) demonstrate the international equivalence of their calibration and measurement capabilities (CMCs). This allows signatory NMIs to recognize each other's measurement standards and the calibration certificates that they issue.[35] Therefore, the NMI of state parties and associates must be actively involved in the country's participation in the activities of BIPM's CIPM.[36]

2.1.2. THE OIML CONVENTION

The convention establishing an international organization of legal metrology (OIML Convention)

[33] BIPM. The Metre Convention. Available at: https://www.bipm.org/en/metre-convention

[34] Idem

[35] OIML (2020). D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

[36] In addition to coordinating the CIPM MRA and working at the governmental level to address global measurement issues, the BIPM establishes and maintains measurement standards that are used as the basis for comparisons with NMIs at the highest measurement level. NMIs of Member States can take part in activities of the BIPM including, but not limited to, measurement research, measurement standards, calibration and inter-laboratory comparisons. With some limitations, this is also open to the Associate States and Economies.

was signed in Paris in 1955, creating the OIML as an intergovernmental treaty organization that:

- Develops model regulations, technical standards and related documents for use by legal metrology authorities and industry;
- Provides mutual recognition systems that reduce trade barriers and costs in a global market;
- Represents the interests of the legal metrology community within international organizations and forums concerned with metrology, standardization, testing, certification and accreditation;
- Promotes and facilitates the exchange of knowledge and competencies within the legal metrology community worldwide;
- Cooperates with other metrology bodies to raise awareness of the contribution that a sound legal metrology infrastructure can make to a modern economy.[37]

2.2.

GLOBAL QUALITY NETWORKS (GQNS)

In the case of GQNs, public and private QI institutions join these self-regulatory bodies of a private nature to benefit from their networks, access to copyrighted information and mutual recognition benefits.

All members of these bodies must abide by their rules to achieve international recognition by their peers and reap the benefits of this recognition. ILAC and IAF, which are in the process of merging to form one single entity (GLOBAC), deal with international and mutual recognition arrangements between accreditation bodies. Additionally, ISO and IEC serve as global quality networks for national standardization bodies, developing international technical standards that are voluntary, consensus-based, and market relevant.

In general, membership in GQNs takes place via a representative institution in each country. Voting procedures in GQN institutions are regulated in their by-laws. Commonly, they allow one vote per member institution. However, they may also indicate that certain voting rights may be limited to one country delegation only. However, in the case of accreditation, some regional GQNs and GLOBAC have distinct historical membership and voting arrangements. In countries in which distinct reasons necessitate the existence of more than one technical standard development organization, a clear arrangement on how to coordinate the national standardization processes and how to represent the country internationally is required.

[37] OIML. What is OIML? Available at: https://www.oiml.org/en/about/about-oiml/what-is-oiml

2.3.

REGIONAL RULES AND SCHEMES

As indicated, QI systems are hierarchical. This means that, to operate across borders, some elements must be harmonized among QI bodies and with other stakeholders. Therefore, standards bodies, accreditation bodies, and metrology institutes, among others, first cluster together regionally and then globally to form networks of technical bodies, to coordinate their activities, to define the structure and rules of their service and to prepare proposals or disseminate decisions made by the global technical networks (see Table 1 in Chapter 1.1. for these networks).

For example, national QI pillar institutions have created regional bodies to administer mutual recognition arrangements structured to create links to global quality institutions. In principle, these organizations support regional integration institutions and agreements. However, membership in one of these regional bodies is not always a one-to-one reflection of geographical or economic affiliation. There are similar examples for metrology and standardization around the globe.

NSBs have either become members of regional or global standards setting bodies or have entered arrangements with them in other to prepare or access standards.

In some parts of the world, groups such as the Pan African Quality Infrastructure (PAQI) and the Quality Infrastructure Council for the Americas (QICA)[38] coordinate actions among standards, metrology, and accreditation organizations. They ensure that these organizations coordinate, discuss and deal with common issues in their respective regions.

In addition, there are instances where inter-governmental bodies are created by multilateral regional institutions or regional economic communities to ensure regional technical cooperation and integration. These bodies are created to undertake different technical cooperation activities. For example:

- Regional bodies established by NMIs facilitate communication at a regional and international level. These include the Caribbean Metrology Cooperation Committee (CARIMET) from the

[38] See PAQI, https://www.paqi.org and QICA, https://qica.site/es/

CARICOM[39] Regional Organization for Standards and Quality (CROSQ), the Intra-Africa Metrology System (AFRIMETS), the Southern African Development Community Cooperation in Measurement Traceability (SADCMET),[40] and the Andean Metrology Network (RAM) of the Andean Community; they can also propose actions via local NMIs, other regional groups and the BIPM directly.

» Certain political and economic unions such as the EU and the Andean Community have adopted schemes that accept conformity assessment procedures from their Member Countries, thus facilitating trade and promoting regional cooperation.

» In the Caribbean, CROSQ prepares and adopts regional standards for 15 countries in the region, while the African Organisation for Standardisation (ARSO) does the same for 55 countries.

]Overall, regional networks and inter-governmental bodies play a pivotal role in ensuring standardized processes and regulations that facilitate cross-border operations, trade, and mutual recognition among member states. This collaborative approach ensures that QI systems are robust, effective, and globally harmonized. As presented in Chapter 4 below, legal frameworks must allow interaction to take place between regional and international frameworks, internal dialogue to be fostered and decisions to be made regionally; they must also allow individual countries to adopt the decisions, technical documents and interpretations made at the regional level. Failing to do so would make it harder for individual countries to implement technical changes and exclude them from contributing their views and needs when regional schemes are decided upon.

2.4.

OTHER INTERNATIONAL TREATIES AND CONVENTIONS

The WTO has been instrumental in the development and use of QI for trade purposes, given the essential role that QI plays in facilitating international commerce. The WTO has implemented key agreements such as the Trade Facilitation Agreement (TFA),[41] the Technical Barriers to Trade (TBT) Agreement,[42] and the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. These agreements promote the use of international standards and their international harmonization, and the signing of mutual recognition agreements for the equivalence or the acceptance of conformity assessment results. They also foster the use of GQN mechanisms and schemes to facilitate trade.[43]

Specifically, to facilitate trade, the WTO has laid down a guidance document of the Committee of Technical Barriers to Trade on principles for the development of international standards, guides and recommendations with reference to Articles 2 and 5 and Annex 3 of the TBT Agreement. This allows countries to determine which standards could be considered for local use, which have been prepared to be international ones.

Notably, some United Nations (UN) intergovernmental bodies and other UN related bodies are recognized as international technical standard setting bodies. This recognition applies to organizations such as the International Telecommunications Union (ITU), the Codex Alimentarius Commission (CAC), the World Organization for Animal Health (WOAH), and the FAO International Plan Protection Convention (IPPC) for the SPS Agreement. Furthermore, the WTO's TBT Committee has established principles for the development of international standards that are fulfilled by standards developed by IEC and ISO.

Furthermore, other conventions focusing on climate issues, environmentally hazardous substances and products, telecommunications, air and other forms of transportation, animal and plant health, agriculture, and energy (among many other areas) require robust QI institutions and services. For example, the standards and guidelines prepared by the technical groups of the Minamata Convention[44], the UNECE's Globally Harmonized System of Classification and Labelling of Chemicals (GHS) maintained by the entity's GHS sub-committee,[45] and study commissions under several telecommunications conventions[46] are considered international standards. In addition to these, there are many other technical groups working at the international level.

[39] CARICOM: Caribbean Community
[40] PTB (2018) Quality for Africa. Available at: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/publikationen/Regionalkonzepte/PTB_Compact_Africa_EN.pdf

[41] WTO (2014). Agreement on Trade Facilitation. Available at: https://www.wto.org/english/docs_e/legal_e/tfa-nov14_e.htm
[42] WTO (1995). Agreement on Technical Barriers to Trade. Available at: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm
[43] WTO (1995). Agreement on the Application of Sanitary and Phytosanitary Measures. Available at: https://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm
[44] See Basel Convention developments. Available at: https://www.basel.int
[45] UNECE, (2017), Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (Rev.7). Available at: https://unece.org/ghs-rev7-2017
[46] See ITU technical work, https://www.itu.int/en/history/Pages/ConstitutionAndConvention.aspx#gsc.tab=0

3 QUALITY POLICY AND THE QI LEGAL FRAMEWORK

In most countries, the formulation of legislation (primary or secondary, as the case may be) is preceded by policy-making decisions. In most legal systems, policy documents and/or legislative briefs are prepared as part of the legislative process. In some cases, these documents are prepared before a bill is presented to the parliament or national congress/assembly or a comprehensive decree is enacted. This holds true for QI legislation as well. Recently, the most successful QI initiatives have been achieved when a quality policy (QP) is thoroughly discussed, drafted, and adopted before the QI legislation is put into place. QPs are generally developed at the national level; however, prominent examples of regional QPs include African and the Caribbean QPs.[47] QPs cover many issues, including coordination of QI institutions and demand for legal reform. Therefore, QPs serve as an ideal foundation for the development of a QI legal framework.

QPs must cater to the diverse needs and interests of different public and private stakeholders operating in productive, service-providing, technically driven, regulated, developmental, scientific, and innovative environments. They should be based on a unified vision that promotes the core institutions of QI, namely, standardization, metrology, accreditation, and their related quality services.

Furthermore, a QP should consider the guiding principles proposed by the United Nations Industrial Development (UNIDO) and the International Network on Quality Infrastructure (INETQI)[48], such as ownership, coherence, optimization, sustainability, and inclusiveness, and should reinforce key principles that guide QI organizations, such as technical competence, impartiality, independence, neutrality, and non-discrimination towards third parties. Integrating these guiding principles during the development and implementation of a QP allows countries and regions to adapt it to meet their specific needs while ensuring alignment with international best practices. It is also vital to subject the proposed QP to a well-designed inclusive consultation process during its drafting and prior to its promulgation and implementation.

Key principles for the development of a QP are further elaborated in a UNIDO publication titled Quality Policy Guiding Principles. Specific associated sub-principles are provided in this document to aid in addressing relevant issues with a proper understanding, to mitigate against short-term interests and to promote a more holistic, inclusive, and collaborative approach to identifying future needs and securing sustainability for the QI system.[49]

After the QP has been adopted, the legal QI framework should be designed to uphold the key principles governing QI pillar institutions. It should ensure in a systematic way that the QI effectively supports a variety of stakeholders, addressing their needs and expectations in a balanced, simultaneous and concurrent way without compromising any of them.

Moreover, QI is a dynamic system that requires constant revision and improvement. The QP should provide guidelines and principles necessary to maintain and reorientate QI institutions. For example, the QP may include the government's commitment to reviewing and amending existing legislation and promulgating new legislation when necessary.[50]

The QI system, including the regulatory framework, obtains its legitimacy through appropriate legislation and socially and technically valuable practices. To maintain clarity and prevent misinterpretations and

[47] African Union (2019), Africa Quality Policy. Final version adopted by STC-TIM on 3 September 2021 and CARICOM, Regional Quality Policy, Final version published by CROSQ on March 2019.

[48] UNIDO and INETQI (2018), Quality Policy, Technical Guide. Available at: https://hub.unido.org/sites/default/files/publications/QP_TECHNICAL_GUIDE.PDF.

[49] Idem

[50] Idem

legal challenges, QI legislation needs to be clear and precise. While the legal framework is being designed, careful consideration should be given to the planning of QI pillar institutions (including coordination schemes) and their related services. If every QI issue is included in legislation, it will take time and effort later to amend the legislation when technical standards and practices change over time. Therefore, when QI legislation is being prepared, a QP is needed as a tool that provides a general understanding and guidance, and can aid in determining the applicable legal rules and the institutional setting (QI institutions may be public or private entities, as will be explained below). The QP is to be applied to the provision of standardization, metrology, and accreditation services in a given country together with calibration and conformity assessment.[51] [52]

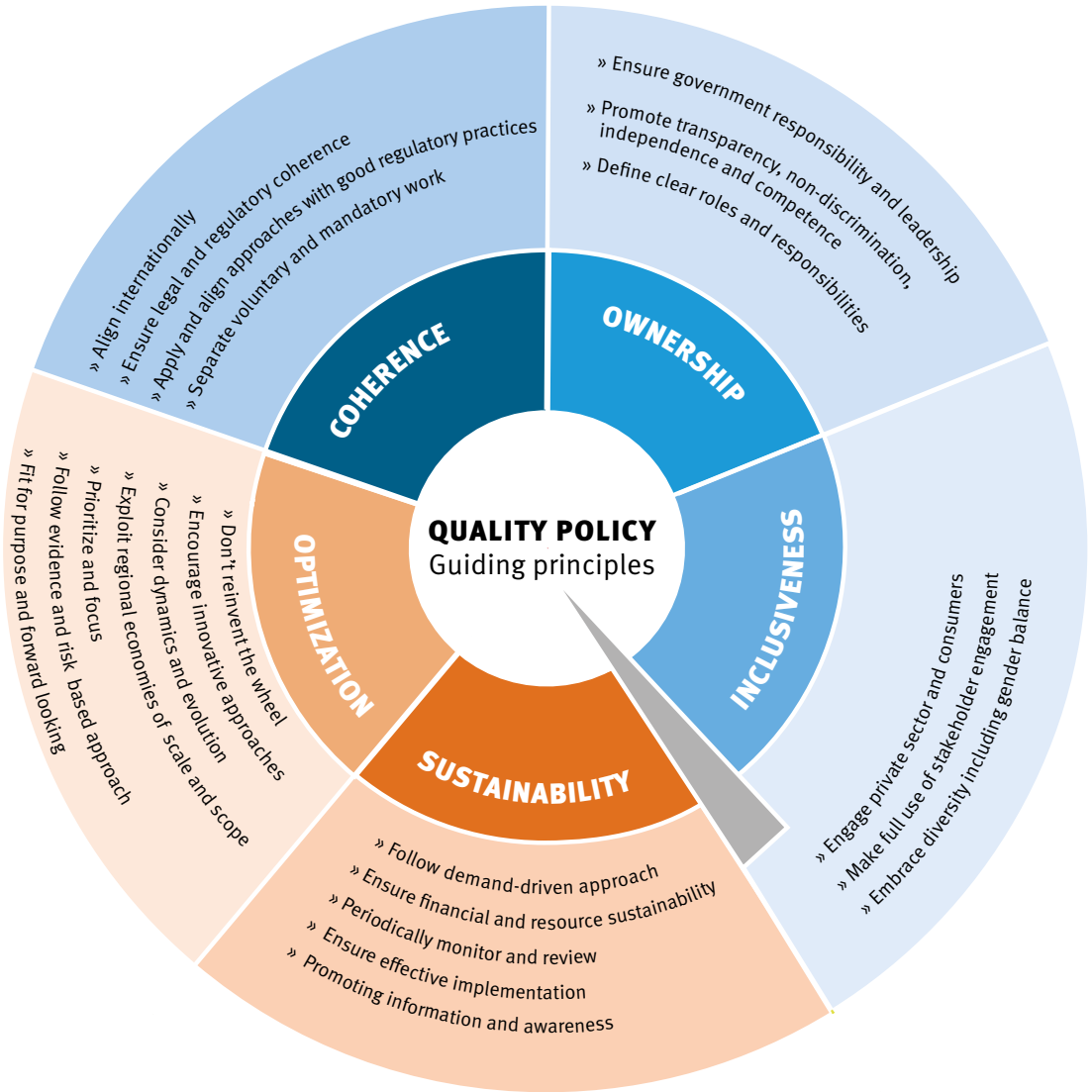
[51]QI legislation may also cover market surveillance and other directly related areas, though other legislation framework may apply.

[52] UNIDO and INETQI (2018), Quality Policy, Technical Guide. Available at: https://hub.unido.org/sites/default/files/publications/QP_TECHNICAL_GUIDE.PDF

Additionally, while developing QI legislation, consideration should be given to other related polices that align with the QP. QI legislation should act as a platform for those utilizing QI services by addressing needs that include technical regulation development, research and development support, and international and local industry trade facilitation.

The legal principles and considerations presented in the following chapters focus on national systems, principles applicable to them, and their interaction with international and regional organizations. These principles and considerations apply to the QI pillar institutions at the reference level (namely the NSB, the NMI, and the NAB) along with secondary level entities (namely calibration laboratories and conformity assessment bodies) that perform services such as testing, certification, inspection, verification, and validation.

GRAPHIC 4 QUALITY POLICY GUIDING PRINCIPLES



UNIDO

4

UNDERSTANDING AND PREPARING LEGAL FRAMEWORKS

4.1.

GENERAL GUIDING PRINCIPLES FOR THE DEVELOPMENT OF THE QI LEGAL FRAMEWORK

When preparing QI legislation, several guiding principles need to be considered. The general guiding principles below are recommended to ensure a clear legal understanding when drafting primary or secondary legislation for QI. In general, primary and secondary legislation should follow QP principles.[53] Nonetheless, additional guiding principles exist for the creation of a legal QI framework, as presented below.

4.1.1.

DEFINITION OF CLEAR ROLES AND RESPONSIBILITIES

Clarity on government leadership and responsibility for functioning and governance (including limitations of governmental action) is crucial in a legal QI setup. Therefore, possible dynamics and QI evolution should be considered in order to clearly define the roles and responsibilities of authorities and QI pillar institutions. Overlaps in roles, functions, and activities between core QI institutions, or among divisions within them, should be avoided. Furthermore, an authority from central government should undertake the coordinating role among core QI institutions, conformity assessment bodies and national regulatory authorities. This will avoid or overcome conflicts, overlaps and redundancies, which can be costly for the country. Finally, it should be noted that, in specific cases, due to certain technical issues, QI pillar institutions may not be able to cope with all the needs of their country. Therefore, QI services may be structured for a region or group of countries to aggregate demand and to use resources efficiently; if needed, such services may be requested and provided by institutions from another country.

4.1.2.

DEMAND DRIVEN SERVICES

The QI legal framework should foster a demand driven approach for QI services, and where possible, competition among service providers in the secondary QI services market. Policy goals are nurtured by good competition conditions such as more than one calibration laboratory being responsible for the dissemination of measurements and several testing laboratories being available, thus expanding testing capacities throughout the country.

[53] Idem

4.1.3.

ALIGNMENT WITH INTERNATIONAL TRADE OBLIGATIONS

The QI legal framework in World Trade Organization (WTO) member countries must consider and be aligned with the WTO Agreements on Technical Barriers to Trade (TBT) and on Sanitary and Phytosanitary Measures (SPS), as well as other related bilateral and regional trade agreements pertaining to QI such as technical standards and technical regulations. At the same time, a good number of regional trade agreements allow QI to be completely or partly organized at the supranational level. This situation is acknowledged in the WTO TBT Agreement.[54] The existence of national or regional QI, as the case may be, should be considered during any technical negotiations or trade concerns raised vis-à-vis a given country in relation to these technical matters.

4.1.4.

ALIGNMENT WITH INTERNATIONAL AND GLOBAL QUALITY NETWORKS (GQNS AND IGQNS) AND WITH REGIONAL INTEGRATION RULES AND SCHEMES[55]

The QI legal framework must ensure that no legal restrictions preempt or make it difficult for QI pillar institutions and other QI actors, including conformity assessment bodies, to benefit from or be internationally recognized by International and Global Quality Networks (herein “GQNs” and “IGQNs”) (see Chapter 2). Alignment with IGQNs is an important instrument for facilitating trade, and overall for enhancing competitiveness; this is also true for regional integration rules and applicable schemes. Coherence with international or regional technical needs and initiatives should be considered in legislation. To achieve this purpose, special relevance to promoting transparency, non-discrimination, independence, and technical competence is needed, as these important concepts are required when addressing IGQNs and regional integration initiatives.

[54] WTO (1995), Agreement on Trade Facilitation. Available at: https://www.wto.org/english/docs_e/legal_e/tfa-nov14_e.htm

[55] For further information, see International/Regional Institutions and Global Quality Networks (GQNs) in Section 4 below.

4.1.5.

FINANCIAL AND RESOURCE SUSTAINABILITY

A QI legal framework should incorporate financial and resource provisions to enable sustainability of the "public good" nature of the three core QI institutions. Access to international standardization and to an internationally recognized system of accreditation and traceability to the SI should be both non-exclusive and non-rivalrous whenever possible. This is particularly true when special planning and budgeting rules for any of the QI pillars are required to be set in legislation.

4.1.6.

QI APPLICATION IN REGULATED AND MARKET DRIVEN AREAS

QI core institutions and their services are an essential source of support for several governmental policies such as public procurement, consumer protection and weather services. QI should also be designed to support a high volume of market transactions. Therefore, the QI legal framework must support more than just technical regulations and other regulations adopted by the state. In earlier QI models, core QI institutions gravitated towards regulatory needs. However, this scenario did not follow the centrality principle of QI vis-à-vis other actors and activities in the country, thus creating quality "silos" but not a single robust and interoperable quality system. Support for regulatory work by QI should be allowed and used; however, at the same time, it should be considered that the state, other entities and the market require several quality services so that they may function properly and advance their legitimate goals and objectives. Therefore, the legal framework should ensure that QI is applied in regulated and driven areas.

4.2.

QI LEGAL FRAMEWORK(S)

Legislation serves as a means to achieve a purpose rather than being an end in itself. In the context of QI, it is a necessary tool to provide national QI institutions with a solid regulatory foundation for their orderly and sustainable work.

It is important to recognize that, since legal systems around the world differ, each country must decide what elements to include in their QI legislation while complying with their constitutional, budgetary, taxation, administrative, labor/civil service, and other relevant rules. When drafting a legislation, technical understanding of QI and legal drafting assistance is advised.

Legal systems can be broadly classed as either common law or civil law systems. Although they operate differently, they achieve similar legal outcomes. When implementing QI legislation, the nuances of these two legal systems must be taken into consideration.

When drafting primary or overarching secondary QI legislation, it is recommended to include the necessary provisions in it and assess if certain aspects can be addressed in secondary legislation. Providing room for secondary legislation in all areas in which primary legislation is not required will give QI institutions a more flexible and balanced legal framework that can be more easily adapted to changing national and international conditions.

As indicated above, the foundation of QI legislation has been more recently derived from overarching QP "ground rules". To foster progress effectively, such a foundation must itself contain essential ground rules for establishing and developing QI that are neither excessive nor insufficient. Where a country decides to cover all or most of these aspects through either an overarching QI legislation or individual acts on standards, accreditation or metrology, the following recommendations should be considered:

- Be as concise and simple as practicable, while providing enough detail to address the country's policies involving QI subject matter.
- QI legislation should provide sufficient flexibility to allow for changes in policy, technologies, and international developments without having to change the law itself, leaving such details to decrees, regulations, and other legal instruments.
- To fulfill the above principle, QI legislation needs to adopt rules and definitions laid down by international and global quality networks (IGQN and GQN) of intergovernmental and other transnational and global technical organizations. This is the case for ISO, IEC, ITU, WMO and FAO Codex Alimentarius standards, among other technical standard setting bodies. If these "special rules and definitions" are not incorporated, it will create difficulties for local QI institutions to interact vis-à-vis their local or international counterparts or fellow institutions that take part in IGQNs. For example, non-acceptance of conformity results usually makes it impossible to exploit the possibilities of international trade.
- The terminology and other technical words or procedures presented by the technical standards above are similar but not identical to

generally accepted legal terms and definitions; in some cases, they may even have different meanings. When drafting legal texts, it should be considered that these two languages (legal and technical) may have particular and substantial connotations or may have an exceptional use depending on the context.

» Legal drafters should also consider whether the legal framework should include interpretation rules, depending on the legal nature of the institutional framework proposed (private or public), its governance, procedures, etc. It should be clear in which cases the rules support a nurturing environment for QI institutions and, in which cases the activities of public institutions need to be limited to ensure compliance with the constitution or other laws.

The major components that legal systems should include for QI legislation are as follows:[57]

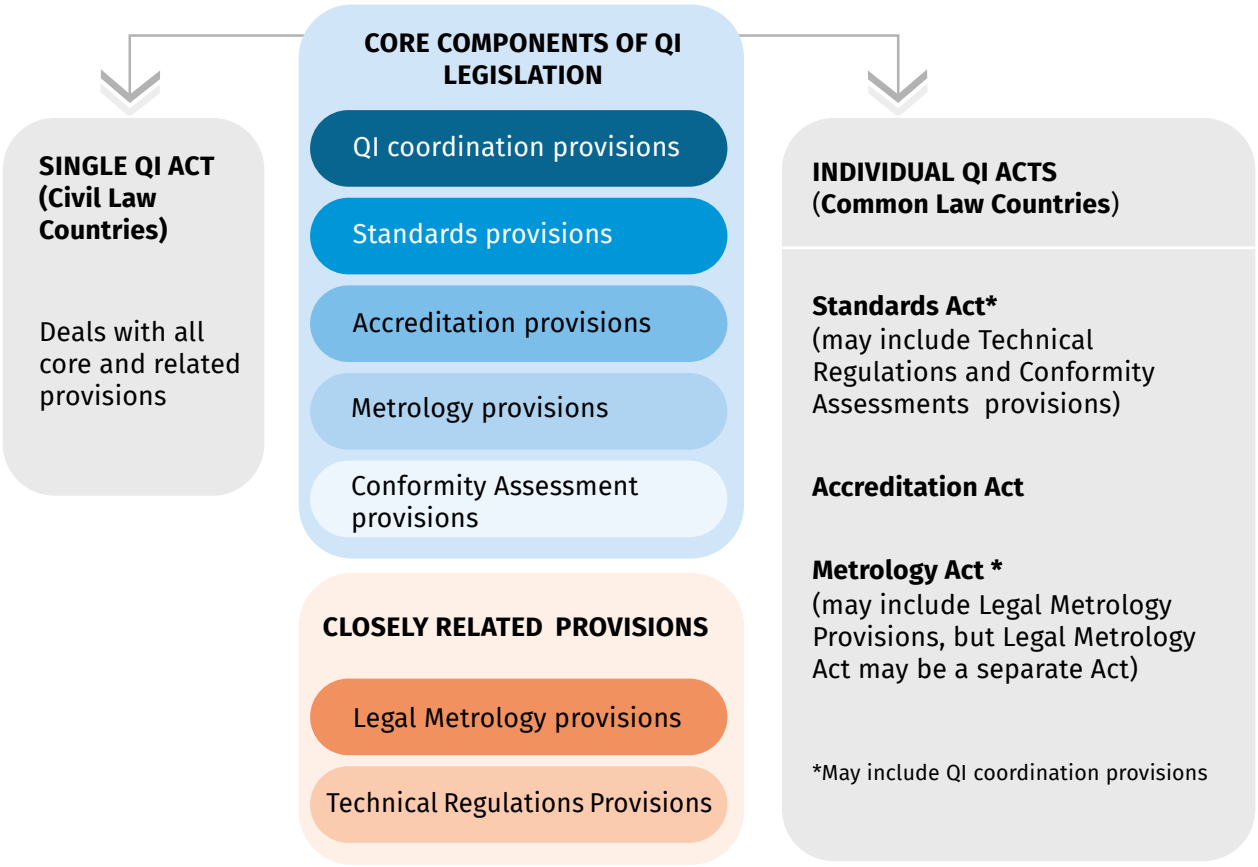
[57] UNIDO and INETQI (2018), Quality Policy, Technical Guide. Available at: https://hub.unido.org/sites/default/files/publications/QP_TECHNICAL_GUIDE.PDF

4.2.1. QI LEGISLATION

» Standards Act: Provides for the development and publication of national technical standards and their legal standing and allows them to be referenced within other pieces of national legislation to form different regulatory schemes. This act ensures the creation, designation, legal nature, and responsibilities of the NSB, the adoption of technical standards, and the publication of the title and number of the adopted technical standards, activities and finances.

Standardization services set up may take different forms. Services may be provided by a regional body or by national bodies. Some countries have different standard setting bodies, some of them working in separate areas, or even, as in the case of the United States, in direct competition with each other.

GRAPHIC 5 TYPES OF QI LEGISLATION



PTB[56]

[56] PTB, based on the work of Ramón Madriñán, international expert in Law and Quality Infrastructure.

Annex 1 presents the main legal issues that need to be considered by interested persons when drafting or amending a standards act. These elements are:

- Legal standing of technical standards
- The national standards body as a legal entity
- Governance of the NSB
- Financial provisions of the NSB
- Main administrative provisions of the NSB
- The formal system of the NSB
- Technical committees
- Technical standards setting process
- Technical standards development organizations
- External relations and recognition of the NSB

METROLOGY ACT:

- Provides for the adoption of the International System of Units (SI) in the country, as national measurement units and the establishment and maintenance of national measurement standards. This act should also provide for the establishment of the NMI, its governance, responsibilities, activities, and finances (including applicable fees' legal framework and disbursements - such as international membership fees). Due to the nature of metrology as a public good, it is customary to have a public entity providing calibrations using national reference measurement standards or working with other designated institutes (DIs) in the country or region to supply them.

  Depending on each country's legal system and especially for Civil Law countries, accession to the Metre and OIML Conventions may require the adoption of the treaty by an act of parliament. In addition, some countries require such acts to be reviewed by a high court such as the constitutional court of the given country.[58]

  The local and/or regional systems to establish metrology and disseminate measurements should follow the best practices indicated herein in order to be effective.[59] As indicated by the OIML, laws and legal requirements interact with metrology in two main ways, as presented below.

- Laws often provide the framework in which metrology in a country or economy operates – for instance, requiring the use of specific measurement units for certain purposes, establishing the authority of a NMI, or providing the basis for public funding of a national measurement system. This aspect is further developed in Annex 2 and covers the following topics:
  - Basic legal metrology determinations
    - Legal standing of measurement units and national measurement standards
    - The national metrology institute (NMI) as a legal entity
  - The NMI's governance
  - Financial provisions of the NMI,
  - Main administrative provisions of the NMI
  - The NMI's laboratory management and recognition of its measurements
  - Designated institutes (national metrological reference laboratories),
  - External relations and recognition of the NMI
  - Many regulations related to trade (e.g. consumer protection), health, safety and environmental protection set measurement-based requirements and indeed requirements for the measuring instruments used for such purposes. It is this second area that is most usually regarded as "legal metrology". The regulatory aspects of legal metrology are expanded in Annex 5.

In addition, as indicated by the OILM/BIPM,[60] while common needs of all societies result in many common concepts relating to metrology being used in all countries, the terms associated with the concepts may be different from country to country (even for the same language), and so it is important that a single vocabulary be used and implemented in a country's Metrology act.

For detailed information on metrology and its relationship to the legal framework, please refer to OIML's Guide (D-1) and BIPM-OIML publications titled *National Metrology Systems – Developing the institutional and legislative framework* (2020), the International Vocabulary of Terms in Metrology

[58] See for example, COLOMBIA- Laws 1512 and 1514 2012 and Constitutional Court Opinions C-822/12 and C-621/12.

[59] OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

[60] OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

(VIM) [61] and the International Vocabulary of Legal Metrology (VIML).[62]

ACCREDITATION ACT:

» Provides for the use of accreditation as the primary means to denote technical competency of conformity assessment service providers. This act should also provide for the establishment of the national accreditation body (public or private) (or in its absence, designate the regional or other national body as the *de facto* national body), its governance, responsibilities, procedures, activities, and finances.

Accreditation services may also take different forms. Services may be provided by a regional or national accreditation body. For different technical and financial reasons, most countries have only one accreditation body. There are, however, some exceptions such as the United States, where accreditation bodies are in direct competition with each other, even though they compete within a particular legal system.

Annex 3 presents the main legal issues that need to be considered by interested persons when drafting or amending an accreditation act. These elements are:

- » Legal standing of accreditation
- » Legal standing of national accreditation body
- » Governance of the AB
- » Financial provisions of the AB
- » Main administrative provisions of the AB
- » Accreditation process of the AB
- » External relations and recognition of the AB

» Legislation on conformity assessment bodies: Provisions that specify the status of conformity assessment services, who provides them and how, and the way in which such services are realized, as well as how they are used by the government and private parties. Additionally, legal considerations for the use of QI services in areas such as legal metrology and technical regulations should be addressed.

Conformity assessment service providers take different legal forms. They can be public or private bodies. Private bodies may be commercial enterprises or non-for-profit organizations. They may operate in only one city or region or have many offices or subsidiaries

Annex 4 presents the main legal issues that need to be considered by interested persons when dealing with conformity assessment services. These elements are:

- » Legal standing of conformity assessment and calibration services
- » Legal entity of conformity assessment bodies and calibration laboratories
- » Protection and support to accredited services.
- » The accreditation process for CAB's and calibration laboratories
- » Designated CABs
- » Registration of trained auditors

» QI coordination provisions. As presented in Chapter 1, there is also demand for active coordination between the core QI institutions. Therefore, national legal rules must ensure centralized QI coordination. There is no single correct way to set up QI coordination, but some examples are provided below:

- Directors or CEOs of the NSB, NMI, and NAB attend each other's council or board meetings as observers in order to ensure understanding and promote institutional coordination for actions and projects.
- The government may establish a national quality council (NQC), forum, or similar platform where all QI stakeholders can provide input and raise issues regarding the QI needs of the country.

Larger or extended coordination may also be needed in the country with regulators and policymakers who interact with QI pillars and rely on QI services. However, it is advised to hold central QI coordination meetings before and after any extended coordination efforts are undertaken.

[61] OIML (2007) OIML V 2-200 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), Edition 2007 (E/F) Available at: https://www.bipm.org/documents/20126/54295284/VIM4_CD_210111c.pdf

[62] OIML (2022) International Vocabulary of Legal Metrology (VIML) – Digital Edition 2022 Available at: http://viml.oiml.info/en/index.html

4.2.2.

LEGISLATION CLOSELY RELATED TO QI

» The QI coordination body in a given country should always consider the proper implementation of instrumental international trade and technical agreements to allow national QI to be deployed and maintained appropriately. Countries do not need to have all QI services established within their borders. They should allow regional and foreign QI services into the country, particularly to ensure that all policies, regulations, the market and other processes and services operate correctly. However, local and foreign QI service providers have the right to equal treatment, under the legal and technical conditions set out by Article 6 of the TBT Agreement vis-à-vis any other exporting Member. Under the same Article, balanced trade relations must also be maintained via technical mutual recognition agreements between governments and memorandums of understanding among regulators.

» Legal metrology provisions are essential for regulating the control of measuring equipment used in various sectors including trade, health services, environmental control, and law enforcement. These provisions should cover offenses, penalties, and defenses related to legal metrology, along with specific requirements for pre-packaging consumer commodities. The legal metrology provisions should establish a dedicated department responsible for overseeing and enforcing the legal metrology regulations. This department's governance, responsibilities, activities, fees, and finances should be clearly outlined to ensure effective implementation. See more details in Annex 5.

» Technical regulation framework provisions that deal with the preparation, adoption and application of technical regulations may be included but must be separate from the provisions outlined in the standards act. However, the QI system should be designed to complement legal arrangements on technical regulations/market surveillance. These arrangements are crucial in facilitating the development, adoption, and implementation of technical regulations while ensuring the use of QI services in a coordinated manner across all responsible ministries and their agencies in the country. This in compliance with the WTO TBT Agreement.[63]

» The elements above have some practical differences depending on the legal system in place. On the one hand, some countries that follow civil law have considered an overarching "national quality law"[64]. In some cases, where allowed by the local legal system, comprehensive QI secondary legislation[65] has been considered that consolidates the rules for technical standards, metrology, accreditation, legal metrology, and technical regulations to ensure consistency and coordination among the core QI institutions and the different government agencies. Such a legislative text may include QI principles and a QI oversight committee to (i) ensure government responsibility and leadership and, (ii) guide the coordination and development of QI institutions in an articulated and coordinated way (governance). On the other hand, because many common law countries prefer separate QI acts, institutional mechanisms need to be put in place in primary law to ensure leadership and governance of the entire QI system and to achieve effective implementation in the same terms described above for civil law countries.

[63] WTO (1995), Agreement on Trade Facilitation. Agreement. Article 6. Available at: https://www.wto.org/english/docs_e/legal_e/tfa-nov14_e.htm

[64] For example: Legislative Assembly of the Republic of Costa Rica (2002), National Quality System Act No. 8279. Available at: https://www.ecolex.org/details/legislation/ley-no-8279-sistema-nacional-para-la-calidad-lex-faoc067716/#:~:text=La%20presente%20Ley%20tiene%20como%20prop%C3%B3sito%20establecer%20el,confianza%20en%20la%20transacci%C3%B3n%20de%20bienes%20y%20servicios.

[65] For example: Presidency of the Republic of Colombia (2015) (2015), Presidential Decree No. 1074. Chapter 7. Available at: https://www.funcionpublica.gov.co/eva/gestornormativo/norma.php?i=76608

5

GUIDELINES FOR THE USE OF QI IN SECTORAL POLICIES

Governments intervene at the sectoral level through various policy tools. These instruments include:

- policy making
- regulation drafting and implementation
- fiscal policy interventions, including:
  - taxation
  - budget allocation and spending (incl. public procurement, provision of government services and their promotion)
  - licensing
- monetary policy

The first three types of state intervention are particularly relevant when analyzing the relationship between QI and sectoral policies, regulations, and their implementation.

QI, as an internationally recognized and interconnected system, plays a dual role in supporting the implementation of sectoral policies. Firstly, it serves as a platform for exchanging globally accepted technical information, knowledge, and expertise in national, regional and international expert settings[66]. Secondly, it provides technical and reliable solutions to sector-specific practical problems, including standardization, accreditation, metrology, and testing, inspection, product certification, validation, and verification.

This chapter elaborates on two main aspects: general and legal considerations to be observed by sectoral authorities to use and respect basic tenets of QI when fulfilling their sectoral needs.

Ideally, the utilization of QI services within sectoral policies, including regulations, should be seamless. It is essential that sectoral authorities make use of QI fora and services in a way that is neither excessive nor improper. The goal is to ensure a harmonious integration of QI into the framework of sectoral policies, without imposing unnecessary requirements or creating undue disruptions.

[66] For example, international standards setting bodies, such as different UN agencies, ISO, IEC and others.

5.1.

INTERACTIONS BETWEEN SECTORAL AUTHORITIES AND DIFFERENT QI INSTITUTIONS

The interaction between sectoral authorities and QI needs to be consciously planned, defined, and managed over time. Sectoral authorities should understand the role and functioning of QI institutions and instruments and the importance and benefits of using QI, while recognizing its inherent limitations. This collaboration between sector authorities and QI institutions may not happen naturally. Therefore, such authorities should be willing to consciously interact with the heads of the QI pillar institutions and, for certain functions, should be allowed by law to participate in relevant sectoral market-driven technical and international mirror committees on technical standards alongside other technical groups, boards, and committees. In addition, a group or council may need to be instituted for these conversations to occur on a regular basis.

Policymakers should maintain a fluid conversation with other authorities responsible for QI in the country and with the responsible persons in the local/regional existing NSB,[67] AB, and (as the case may be) NMI, as well as the regulatory, customs and market surveillance agencies in the country, as needed. This is particularly important when sectoral policies are being drafted or revised. Also, establishing and maintaining a productive dialogue with the CAB and trade associations or their representatives is key to understanding implementation issues.

Sectoral regulators, especially when preparing or revising technical regulations or other secondary legislation that relies on technical issues, need to follow the aforementioned suggestions and possess a profound knowledge of the market and the specific QI services required. If QI services are necessary in order to comply with a policy or regulation, CAB must be aware of the requirements and applicable rules to decide whether to invest in new services and accreditations.

Public procurement & licensing authorities must not only have the appropriate knowledge of the goods or services procured or licensed but must also consider the applicable technical standards and conformity assessment to be utilized for

[67] ISO has proposed a step-by-step guide for effective engagement between NSBs and public- policymakers. See ISO (2023), Standards and public policy: A toolkit for national standards bodies. Available at: https://www.iso.org/publication/PUB100476.html

each case. A general policy that considers quality as a basis for tender offers must be considered alongside other relevant factors such as price and experience.

Responsible officers for the provision of government services should be aware of what QI services are available locally, regionally, and internationally, including those of the regional or national metrology institute, that might assist responsible persons in the provision of government services. For example, when providing medical tests, consideration should be given to implementing the ISO 15189 management system, which specifies requirements for quality and competence for medical laboratories, to using relevant reference materials and to accrediting the service. If new or additional services are needed, fruitful communication with QI institutions and the CAB needs to take place.

QI is essential for international trade: for example, the WTO TBT Agreement recognizes the significant contribution that international technical standards and conformity assessment systems provide as a means to improve production and market efficiency and facilitate international trade.[68] As indicated, QI is key to complying with international buyers, industry requirements, and the target country or region's technical regulations. International trade and QI require a constant dialogue between exporters, the CAB, customs and trade related institutions, industry officials and the heads of QI institutions. Interaction among these parties normally prioritizes and defines a strategy and resources to ensure active participation in international or regional technical standard-setting fora, to study the impact of technical regulations during the drafting process, and to adopt and comply with applicable international requirements.

To increase and diversify production, QI has a prominent role in promoting productivity and competitiveness in the country. Continuous coordination in each economic sector between the CAB, the heads of industry, and QI institutions is highly suggested. Sectoral policymakers and regulators should be invited to meetings to consider private sector views.

QI services are also required for monitoring resources, elements and materials. More recently, QI has been called on to play an important role in quantifying the existence of certain resources (for example, the existence of endemic forests in an environmental project) and may expand to other elements and materials. In some of these cases, conformity assessment results may serve as a basis for financial instruments or tax compensation schemes. To realize this goal, all relevant authorities, the CAB, and interested parties must come together and assist in the definition of policy matters and the existence/development of specific QI services.

Science, research, and development also rely on QI services. QI elements such as a new or improved measurement may be the subject of study. For example, the inter-comparison of scientific studies could be compromised if measurements used are not comparable. Official science and technology programs must consider these elements. Official science and technology programs must also contemplate the needs of society and industry and interact with universities and science and technology institutes.

It is important to note that unplanned shortcomings in utilizing QI services can delay or hinder the adoption of policies or regulations. Due to the nature of preparatory activities, QI does not adjust to policy or regulatory incentives at short notice. Sometimes, when a policy or regulation has not been properly communicated among interested parties or has been changed frequently, there may be no interest in investing in more costly QI services such as more resource demanding testing laboratories.

In addition, QI investments require not only resources but time. Process adaptations including equipment calibration (which sometimes needs to take place in a different country), personnel training, and the time required to seek and obtain accreditation cannot be achieved overnight. To determine an appropriate adaptation period, QI institutions are in a better position to provide such information to legally competent planning or sectoral authorities.

Some QI service developments require significant investments. As budgets are limited, sectoral authorities are encouraged to have meaningful conversations with their national and regional peers to identify services and equipment that can be used as a common resource – for example, a testing machine located in a national technical institute. This is especially true in areas such as chemistry where equipment is costly and requires dedicated personnel.

5.2. LEGAL CONSIDERATIONS BY SECTORAL AUTHORITIES FOR THE USE OF QI

[68] WTO (1995), Agreement on Trade Facilitation. Preamble and Articles 2.4 and 5.4.

5.2.1.

ACTIVE PARTICIPATION IN THE FORMULATION / ELABORATION AND IMPLEMENTATION OF THE NATIONAL QUALITY POLICY AND LEGISLATION

Commonly, among national authorities, one ministry is responsible for the preparation of the national quality policy (NQP) and related legislation on technical standards, accreditation, and metrology. Sectoral authorities that utilize or have the potential to utilize QI networks and services must be made aware of any proposal involving the formulation of or amendment to the NQP or any related legislation. Sectoral authorities must ensure that the NQP and related legislation are drafted in a manner that allows their sector to benefit from QI group discussions and services. Similar considerations should be followed when the NQP or applicable legislation is prepared at the regional level.

5.2.2.

SELF-RESTRAINT AND COORDINATION WITH OTHER POLICIES AND AUTHORITIES

Sectoral authorities should view QI as a shared resource to be used in coordination with other authorities and interested parties such as industry and universities. Therefore, when formulating legal texts to consider the use of QI services or support from the local or regional QI, sectoral authorities must avoid overstepping in ways that create an imbalance or restriction in QI structure, resources, or results. For example, when two authorities require conformity assessment services for the same product or element, they should consider alternatives to avoid the duplication of conformity assessment services or calibrations. To this end, sectoral authorities must have a reliable and agile communication channel that allows them to coordinate planned QI related legal actions among themselves and with QI institutions. In addition, when drafting technical regulations that require QI support, regulators should follow globally accepted regulatory improvement and good regulatory practice principles and practical methods.

5.2.3.

ACTIVE PARTICIPATION IN ADVISORY / GOVERNANCE BOARDS OF QI INSTITUTIONS

QI institutions have by design certain advisory or governance boards. For example, as indicated in Chapter 4 and Annex 3, ABs must have a governance board where indirect interests to accreditation must be represented. As the government has an indirect but significant interest in accreditation, regulators involved in regulated or strategic products and services should be designated in a manner previously defined in legislation or the AB's by-laws – for example, by designation from a higher authority or the QI coordination body to have a chair in such a body to ensure the required balance in the AB's governance. NMIs and NSBs normally have an advisory or technical board to guide strategic or technical decisions.

The government delegates to these boards and bodies must be legally designated. The designation of government authorities should be made official, and attention should be paid as to how such official delegations are made in a manner that meets all applicable legal requirements. In addition, the designated officials must have the necessary time, interest, and basic knowledge to ensure active participation in these bodies. Wherever possible, the NQP or quality legislation (including technical standards, accreditation, and metrology legislation) should specify which ministry, agency or department's representatives should be designated to sit on these boards.

5.2.4.

ACTIVE PARTICIPATION IN TECHNICAL STANDARDIZATION COMMITTEES AND USE OF NATIONAL AND INTERNATIONAL TECHNICAL STANDARDS

Technical standardization committees define the technical elements incorporated into technical standards. In parallel, mirror committees are responsible for coordinating and establishing national positions concerning international technical committee advancements. In addition, these committees act as a vital link between international technical developments and local stakeholders, facilitating effective communication and collaboration in both directions.

Unless it is not considered a regular government function in the given country, sectoral authorities must ensure the participation of officers in standard-setting technical committees by legal mandate, either through national quality legislation that ensures broad participation of sectoral authorities' representatives, or through their own applicable legislation that defines the participation as a regular function of sectoral authorities. In addition, it is crucial that such authorities identify and determine which specific technical committees are currently or potentially involved in the development of technical standards

relevant to their respective policies. By proactively engaging in these committees, sectoral authorities can effectively contribute to the development of technical standards that align with their objectives and priorities.

Once relevant committees have been established, it is essential that the public officials concerned register with the NSB as expert members of such a group or groups. Committee meetings are usually held at regular intervals; thus, time must be set aside to ensure participation. The position of sectoral authorities must be presented in a clear and technical matter, even if such a position is not ultimately accepted by the committees' participants. It should be noted that, when drafting a technical regulation, regulators may deviate from actual technical standards when important situations require consideration (e.g. assuring the fulfillment of the legitimate objectives), as indicated by the WTO TBT Agreement.[69]

When drafting policies or legislation supported by QI services, sectoral authorities must consider and include in their drafts the applicable technical standards that industry must comply with (in the case of technical regulations) or that other actors should use in other policies or legal documents. If a national standard has been developed by the NSB, the sectoral authority may reference such a standard in the respective policy or legislation. A local standard generally provides easier access to local stakeholders. However, in the event that the NSB has not developed a national standard, or such a standard does not provide the technical solution sought by the government, a foreign, regional, or international standard may be referenced instead. In the realm of technical regulations, certain rules such as Article 2.4 of the WTO TBT agreement dictate that, when preparing such technical regulations, they should be grounded in international technical standards. Nevertheless, exceptions may arise when objective circumstances demonstrate that adhering to the international standard would hinder the government's attainment of legitimate objectives.

With the exception of technical standards developed by multilateral bodies like UN institutions and the Codex Alimentarius Commission (CAC), industry market-driven standards are generally proprietary documents. This means that they are protected by copyright laws, which grants the NSBs the authority to control current and future versions of these technical documents. Consequently, these market-driven standards cannot be directly incorporated into policies or regulations. When such standards are referenced in government documents, those impacted by the policy or legislation will be required to obtain a printed or digital copy of the respective standard at a cost or visit the NSB's library, which houses a collection of regional, international and foreign technical standards for reference. It is important to note that changing these rules has a detrimental effect for the development of market-driven industry standards in both the short and long term.

[69] WTO (1995), TBT Agreement. Article 2.4.

5.2.5.

MEASUREMENT UNITS AND METROLOGICAL TRACEABILITY

Measurement specifications used in sectoral policies and regulation should use the measurement units, writing rules and exemptions defined in the metrology law and secondary metrology legislation. Furthermore, ensuring metrological traceability of all measurements to the SI, is a key element to consider in these cases and is normally achieved through international measurement standards. Therefore, whenever measurements are required, they must be traceable to national measurement standards that are themselves traceable to the SI.

5.2.6.

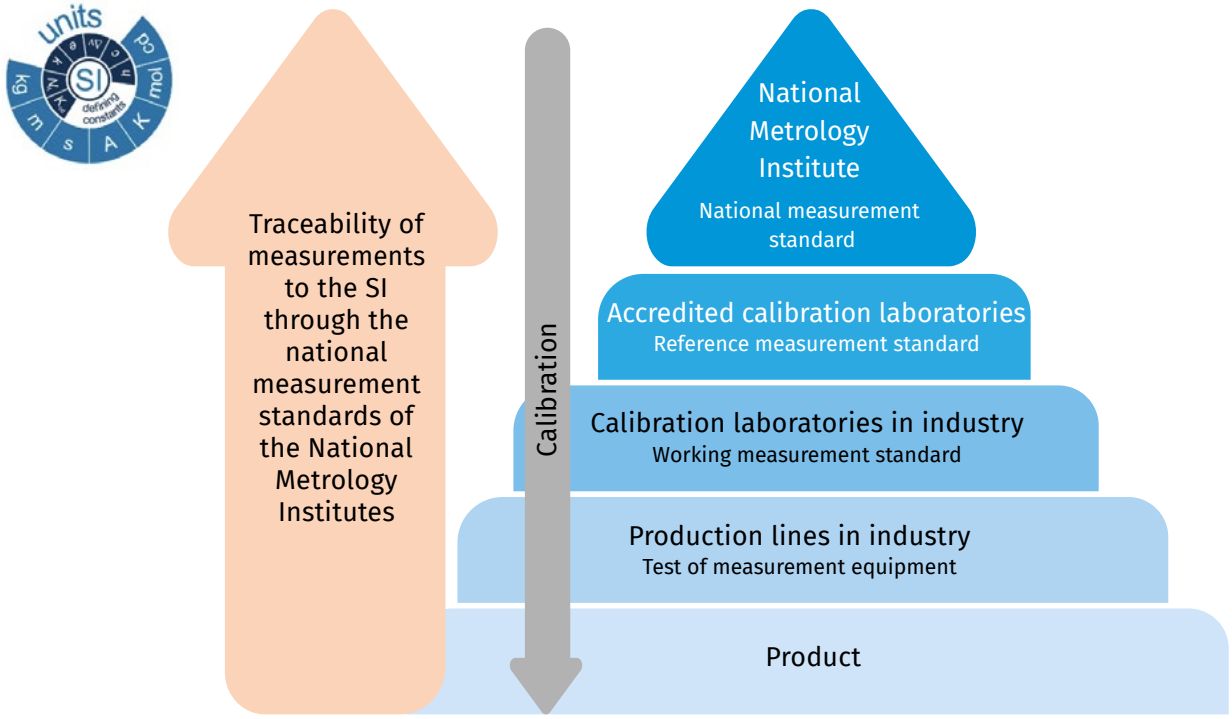
USE OF ACCREDITED CABS

Sectoral policies, including regulations, can benefit from QI services available both domestically and, in some cases, from outside the country. These services include product certification, testing and inspection. In such instances, sectoral authorities should outline the advantages of utilizing these QI services. Furthermore, whenever possible, they should allow the results provided by accredited (and internationally recognized) CABs to be used as evidence or validation/verification of a fact or requirements specified in policies or regulations. For instance, they may be used to determine compliance with the minimum permissible level of heavy metals or pesticides contained in food and foodstuffs).

When a sectoral authority determines that a specific policy or legislation will be supported by QI services and that those services are to be provided by external CABs supporting the industry, this policy or legislation must define:

- the specific aspect(s) of government intervention that will be subject to calibration, testing, inspection or other evaluation by an external CAB
- the technical standards or technical documents that must be met by external CABs while performing such services

GRAPHIC 6 TRACEABILITY TO THE SI



PTB

- the type of technical service required (e.g., product certification, inspection) to be rendered by an external CAB to fulfill the government needs or demonstrate the fulfillment of obligations
- that external CABs are legally authorized to perform such services
- that accredited external CAB should provide the required conformity assessment services whenever possible
- who should remunerate CABs for their services
- what happens if no external CAB is accredited or ready to provide the services required
- when conformity assessment services may be provided outside the country (for example when (a) product certification takes place via an accredited certification body and its AB has signed the IAF's multilateral recognition agreement which the local AB is also a member to or (b) when a government-to-government multilateral recognition agreement has been executed)
- if CABs need to be registered beforehand to perform such services

Finally, responsible authorities must ensure that market competition among CABs is ensured by policies or regulations. QI service providers should compete to achieve optimal results. It is important to recognize that QI cannot ensure that all CABs needed under a policy or regulation will be ready to provide accredited services at the same time. Therefore, technical regulations should consider, whenever needed, that conformity assessment provisions must not enter into force until a defined number of CABs are ready to compete technically and economically. Otherwise, a single CAB or dual CABs may attempt to raise prices to an uncompetitive level or set undesirable response times or service conditions that may affect the implementation of a policy or legislation.

6

QI AND LEGAL ASPECTS OF TECHNICAL REGULATION FRAMEWORK: SECTOR EXAMPLES AND SPECIFICATIONS

There are different types of regulations, and regulators may utilize QI services in different forms[70]. Nevertheless, and without prejudice to any tort rules and claim procedures, QI services have proved to be very valuable in the regulation of products. It should be noted, however, that most legal systems have two different types of systems for regulating products: the general manufacturer/importer responsibility system and the technical regulations as such.

The general manufacturer/importer responsibility system or recall system is a general product responsibility or umbrella system (as it covers all marketed products in a jurisdiction) that allows the enterprise responsible for a defective product to prevent faulty products from reaching the market or, if they have already reached the market, to recall them. This system normally involves notifying the responsible product safety authorities and defining the parameters of a successful recall campaign. The wider use of this system lowers the use of command-and-control technical regulations and facilitates trade while protecting consumer safety.

In the case of the umbrella system, QI has proven very effective in allowing manufacturers and their related parties (such as providers and importers) to ensure the safety of products and to be able to demonstrate due diligence that either prevent fines or the imposition of damages such as punitive damages by the courts.

Technical regulations, as defined by the WTO, are documents that lay down product characteristics and their related processes and production methods, including applicable administrative provisions with which compliance is mandatory. They may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.[71]

The WTO defines "conformity assessment procedures" as any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards have been fulfilled. Conformity assessment procedures include procedures for sampling, testing and inspection; evaluation, verification, and assurance of conformity; and registration, accreditation and approval as well as combinations of these elements.[72] These procedures are QI services.

The strictest type of technical regulation, most commonly found in formalistic legal systems, is the command-and-control type.[73] These technical regulations generally require products to be tested and certified in a particular way. Once the products pass these conformity assessment procedures, they are accepted by the legal system. In some cases, however, if conformity assessment procedures are too strict or legal evidence is subject to legal restrictions, false positives may occur and end up being prejudicial.

6.1.

KEY CONSIDERATIONS ON TECHNICAL REGULATION ISSUES, INCLUDING THE POTENTIAL USEFULNESS OF QI

As has already been mentioned in other chapters, technical standards are not mandatory, in contrast to technical regulations. However, the WTO Agreement on Technical Barriers to Trade (TBT) promotes technical regulations to be based on international standards. In practice, this can be applied by referencing a relevant standard in a given technical regulation, using the standard under a "considered satisfactory" rule, or by taking the contents of the standard as a basis for the text in the technical regulation.

The following sections present a number of examples of sectors that have benefited from UNIDO technical cooperation programs on QI strengthening. The intention is to provide insight into topics that can potentially develop technical regulations and into how QI would be useful. In this context, there are some cross-cutting topics of global importance whose specific status in sectoral examples will be addressed in each section:

- **Regulatory Impact Assessment (RIA):**[74] Before developing regulations, as part of good regulatory practice (GRP), it is advisable to carry out an evidence-based regulatory impact analysis under a risk-based approach (whenever feasible) following international technical standards. Here, the level of development and availability of the country's QI services must be evaluated, including:
  - Offer of calibration and testing laboratories, reference materials and proficiency testing, when and as required

[70] OECD (2008), Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA). Available at: https://www.oecd.org/mena/governance/41727566.pdf
[71] WTO (1995), Agreement on Technical Barriers to Trade, Annex 1.1
[72] WTO (1995), Agreement on Technical Barriers to Trade, Annex 1.3
[73] OECD (2008), Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA). Available at: https://www.oecd.org/mena/governance/41727566.pdf
[74] See MERCOSUR-PTB (2024). Madriñán, Ramon (Ed.) Regulatory Impact Assessment (RIA) Guide for the Regulatory Authorities of Energy Efficiency Labeling of MERCOSUR. (Spanish) Available at: https://www.mercosur.int/wp-content/uploads/2024/05/GUÍA-AIR-2024-04-VFRP-Esp.pdf See also, OECD (2008), Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA). Available at: https://www.oecd.org/mena/governance/41727566.pdf

- Level of regulatory harmonization with other economies
- Technical capabilities and availability of economic, technical, and human resources in regulatory authorities and market surveillance
- Supply of specialized technical training for industries and conformity assessment bodies

Good regulatory practices, including regulatory impact assessment, are fundamental as a precedent in the design of regulations. However, the implementation of regulatory impact assessment will not necessarily lead to a regulated alternative, as deregulation or "doing nothing" may be the preferred alternative when the "cost" of such regulation—technical, political, economic, social, or environmental—is higher than its potential benefits.

There are alternatives to technical regulations including private standards, codes of conduct/practice, industry self-regulation[1]/co-regulation[2], economic instruments, and educational programmes.

- **Regulatory harmonization:** Recognition of different legal regimes of markets such as the EU, USA and some emerging markets remains an issue and there are initiatives discussing harmonization. However, the differences in terms of classification, authorization and prior/follow-up control prevail in the main regulatory frameworks of reference. A regulatory framework with a general orientation towards international technical standards but (temporarily) accepting requirements and conformity assessment results from other systems (e.g. through equivalence instruments) is a recommendable strategy. It ensures on the one hand the necessary control of imported products and on the other hand the market entry of national products in foreign markets, while taking into consideration international market realities.
- **Mutual Recognition Agreements (MRAs):** Agreements on the mutual acceptance of conformity assessment systems and calibrations may be signed by the governments of the negotiating parties in trade agreements. In these cases, regulators in one country will accept products that are certified in accordance with the recognized system in the other signatory countries, facilitating commerce between different economies.

  These agreements can be bilateral or multilateral. Widely used examples of such arrangements include mutual recognition agreements within international accreditation forums signed by national or regional accreditation bodies. These agreements allow for the mutual recognition of conformity assessment results as long as the conformity assessment body is accredited by a signatory of such agreements and complies with other applicable regional and local rules (for example, as a notified body of the importing country), and as long as it operates in the exporting country's territory, thus allowing it to have direct contact with the goods or production process to be evaluated.[75]
- **Consumer protection:** A very important part of requirements and mandatory legislation for consumer protection is related to claims, labelling and packaging that avoid practices that may create risks or mislead consumers. Product claims, whether explicit or implicit, must be supported by appropriate and verifiable evidence, including lab studies when appropriate. Packaging regulations can vary from country to country and between federal states. In some cases, market inspection schemes are implemented with general guidelines to verify that no harm is caused to consumers through misleading information. In other cases, when there are legitimate objectives to be safeguarded, technical regulations are implemented and the demonstration of conformity is based on the concept of third-party bodies such as certifiers and laboratories. All these elements are constituent parts of a quality infrastructure.
- **Risk-based approach:** The "risk-based approach" used for the formulation and implementation of technical regulations should be based on sound and confident information gathered by accredited laboratories and conformity assessment bodies and other actors of the quality infrastructure as well as via comprehensive studies and empirical evidence. Risk management and risk assessment should be based on corresponding international technical standards.[76]
- **Use of accredited conformity assessment mechanisms:** Conformity assessment mechanisms based on accreditation and international recognition of laboratory competence should be included in technical regulations as the most strongly recommended way to assess the fulfillment of the set requirements. However, the conformity assessment mechanism to validate compliance with a regulation should align with a risk-based approach, thereby avoiding excessive compliance burdens and unnecessary and unjustified obstacles for the entry of low-risk products into the markets.

[75] WTO (2015), Agreement on Technical Barriers to Trade, Articles 2.2 and 2.4.
[76] Breyer (2007), Breaking the Vicious Circle, Cambridge/London, Harvard University Press.

- **Clear mandate for NQI institutions:** NQI institutions should be clearly mandated and linked when supporting the implementation of technical regulations to avoid oversights, overlaps, duplication, and conflicts of interests. Steady coordination between regulatory authorities and QI institutions should be established. For these purposes, it is highly advisable that the concept of QI be understood broadly, starting from the establishment of a QP. QPs are a means to reform, consolidate, refine, and maintain an effective and efficient QI.
- **Public policy linkages**: As previously stated, the need for a QI that is more robust, adaptive, cost-effective, user-friendly and sustainable can be met by establishing a comprehensive and sound QP. In fact, because QPs are often rightly seen as part of a wider development strategy, connections with other public policies become natural. Laboratory services are strategic goods provided through knowledge-intensive networks, so laboratory policies have emerged as a way to make technical capacities more efficient and mitigate potential market discoordination in conformity assessment. In turn, industrial policies, productive development policies, and climate change policies, to name just a few examples, can be supported by a resilient and efficient QI and can be connected via a QP to provide an umbrella for the development of specific downstream regulatory frameworks.
- **Consideration of market-driven private standards in technical regulations:** When incorporating the content of market-driven private standards into technical regulations, the following elements should be taken into account: the likelihood of reducing/increasing discrepancies between practices and requirements for domestic and export markets; the credibility of the regulatory framework; and the role of inspection authorities and procedures. It will also be important to validate the level of consensus and acceptance of such standards to ensure that these instruments are oriented towards harmonization.
- **Obligation of operators:** Business operators hold the primary legal responsibility for ensuring compliance of their products with existing technical regulations. QI and QI services are imperative for auditing, certification testing, inspection, and training. The technical regulations must consider that, in order to operate, product managers must ensure risk management throughout the value chain, including the stages of product design, manufacturing, marketing and distribution. The technical regulations must also ensure that operations and market surveillance authorities establish technical capabilities to fulfill their functions.
- **Development of knowledge capital:** Although it is difficult for regulatory trends to match the dynamics and speed of technological trends, it is necessary for countries to develop adequate knowledge capital to ensure that regulations can be applied and their compliance can be verified. This must address multiple fronts, including knowledge capital in regulated groups to comply with new technical regulations, as well as knowledge capital in authorities to ensure that the products of regulatory activity are consistent, of high value, produce the desired effects, and can also be verified for compliance via personnel, inspection services, and other current and relevant QI services.
- **Advancing the state of the art of an industrial sector:** The adoption of international technical standards as national technical standards supports the objectives of technical regulations in two ways. On the one hand, making national technical standards more accessible for technical regulation processes allows their relevant content to be more easily used in technical regulations. On the other hand, adopting international standards as national technical standards will advance the state of the art of national industry and manufacturing, and thus improve the safety and security of products.
- **Reducing asymmetries of information:** Producers, importers and other actors in the value chains need easy access to information about existing QI capabilities and services to be in a better position to comply with technical regulations. A QI service database or similar could be an instrument to reduce information asymmetries.

In the following sections, four sectoral examples are presented:

6.2.
FOOD SECTOR

The food sector is crucial for national economies, with far-reaching effects on countries' overall economic stability. This section focuses on the QI and legal aspects of the regulatory framework for food and foodstuffs, particularly the spice and fishery sectors given their relevance for international trade. The global spice and seasoning market was valued at USD15.5 billion in 2022 and projected to reach USD 20.2 billion by 2030, while the global fishery trade has grown steadily and reached around USD 193.5 billion in 2022.

Food safety stands as a paramount concern in international trade, given the complexity of ensuring consumer safety across borders. Key global food safety concerns include the spread of microbiological hazards, chemical food contaminants, assessments of new food technologies (such as genetically modified food or GMOs), and strong food safety systems in most countries to ensure a safe global food chain.

Sanitary and phytosanitary (SPS) measures play a crucial role in protecting human, animal, and plant life and health. These measures include all relevant laws, decrees, sanitary and (in some cases) technical regulations (i.e., food regulations), requirements, and procedures such as production methods, testing, inspection, and certification, among other things, and need to be sustained by rigorous risk assessment.

The basic aim of the WTO SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate while ensuring that these rights are not misused for protectionism resulting in unnecessary barriers to international trade. This agreement encourages WTO Member States to establish national SPS measures consistent with international technical standards, guidelines and recommendations developed by the joint FAO/WHO Codex Alimentarius Commission (CAC) for food safety, the World Organization for Animal Health, and the International Plant Protection Convention (IPPC) for plant health.

Notable among the SPS measures developed by the CAC is the latest version of the Hazard Analysis and Critical Control Points (HACCP). The HACCP is a globally recognized food safety management system that is mandatory in many countries, including for food operators. As they play a pivotal role in the regulatory framework governing food safety aspects, regulators have quickly adopted HACCP principles to ensure their food products meet international requirements.

However, while HACCP is widely used by food business operators worldwide, there exist different regulatory approaches in different countries. In the EU, HACCP is mandatory along the supply chain; all food business operators after primary production must have principles of HACCP integrated into their broader food safety management framework. On the other hand, in the US, the Food Safety Modernization Act (FSMA) emphasizes preventive controls and requires all food facilities to have a written food safety plan that includes hazard analysis and risk-based preventive controls.

In addition to HACCP, health certificates (HCs) are also a crucial certification scheme issued based on accredited laboratory testing to ensure food safety. For example, while regulators in seafood-exporting nations are generally equipped to issue HCs in compliance with national or buyer (market-driven) standards, accuracy and traceability in laboratory testing remains a challenge in many developing countries.

Some countries, together with HACCP, also require a country of origin (COO) certificate. For instance, in the fishery sector, COO certificates are required in order to ensure legal sourcing and determine whether preferential treatment is being afforded to specific producing countries.

Furthermore, audits performed by competent authorities in importing countries are also common practice, notably in the EU. Some importing countries such as China, Russia, and select Middle Eastern countries have adopted the EU system as a benchmark. MRAs are also gathering momentum between exporting and importing countries to facilitate trade and recognize each other's systems and certificates.

Other measures applicable in food industry are related to the WTO TBT Agreement in topics such

as labeling and quality requirements for fresh food, where technical regulations should be based on international technical standards.

Beyond legal obligations, buyers often have additional requirements. For example, with reference to the spice and seasoning sector, the Codex Alimentarius Committee on spices and culinary herbs is a subsidiary body of the CAC that develops international technical food standards, guidelines, and codes of practice to protect consumer health and ensure fair practices in the food trade. The interests of the international spice trade are represented in the CAC by the International Organization of Spice Trade Associations (IOSTA). IOSTA has published a General Guideline for Good Agricultural Practices on Spices and Culinary Herbs to prevent contamination. In Europe, buyers require suppliers of dried herbs and spices to comply with the European Spice Association's (ESA) quality minima for products purchased for further processing within the EU. Some buyers in the US use more specific indicators from the American Spices Trade Association (ASTA)'s Cleanliness Specifications. Others relate to food safety, and sustainable and ethical business practices.

Regarding the fishery sector, the CAC updated the Code of Practices for Fish and Fishery Products in 2020 to include generic guidelines and recommendations for the safeguarding of human health and the promotion of fair trade practices in the global capture fishery and aquaculture industry.

While regulators mainly address food safety issues, in recent years, environmental, sustainability and social aspects have become parts of mandatory, market driven requirements set by competent authorities and buyers. For instance, the Sustainable Spices Initiative (SSI) was founded in 2012 as a sector-wide consortium bringing together companies and NGOs active in the spice and seasoning sector. The SSI uses a widely recognized set of international technical standards and auditing systems applied in agriculture, covering critical sustainability issues faced by the spice and seasoning industry.

Furthermore, in Europe, protected geographic indications (PGIs) and protected designations of origin (PDOs) protect products that have unique characteristics linked to their geographical origin with demonstrable traceability. This results in higher quality and safer products, preventing fraud and adulteration. In light of this, countries put substantial efforts into protecting the quality and reputation of their food products. One notable example is Sri Lanka: through the technical support of UNIDO, it received its first PGI from the EU Commission, setting apart its Ceylon cinnamon on the EU market from lower-quality substitutes.

6.2.1

FOOD SECTOR SPECIFIC KEY CONSIDERATIONS ON FOOD REGULATIONS AND HOW QI WOULD BE OF USE

In addition to the general cross-cutting considerations presented in the introduction to Chapter 6, the following sector specific considerations must be taken into account for the food sector.

» Improve policy coherence. SPS capacity needs and priorities should be strategically linked to NQPs. Ensuring policy coherence is especially important when countries pursue a process of structural transformation linked to economic development. It is desirable for coordination and dialogue among the different national authorities that deal with food and QI institutions to be considered in legislation.

» Risk-based approach. Food regulation regimes and related legislation needs to be reviewed and adjusted to meet SPS measures, regional requirements and international best practices. Specifically, there is the need to adopt a risk-based approach within legal frameworks (i.e., to create SPS measures on the basis of an appropriate assessment of the actual risks involved and to determine an acceptable level of risk) and, more importantly, to establish separation of risk management decision making from execution and risk assessment.

» In this context, potential public health risks are a significant concern in the spice and seasoning industry. To reduce this potential risk and eliminate safety defects, food regulations must include qualitative and quantitative values on microorganisms, mycotoxins, pesticides, heavy metals, irradiation doses to be applied, physical factors, use of prohibited colorants and food additives. This can be different from product to product and country to country, based on the risk assessment carried out. International standards provide a good basis of information on requirements.

» Harmonization of technical standards: The lack of harmonization of international technical standards can cause uncertainty within trade, consumer protection and overall market consistency and add costs for exporters, as they need to employ different types of technologies and tests to satisfy different market requirements. Additionally, overlaps of food safety standards and schemes can lead to misunderstandings.

- The NSBs in conjunction with the mandated authority should ensure harmonization of national technical standards with regional and international standards, collaborating to ensure the effective implementation of the SPS agreement.
- In addition, collaborative efforts between trade partners, industry associations, and international organizations must be channeled. Industry associations can advocate for harmonization through active participation in international fora and dialogue organized by international organizations like the Codex Alimentarius Commission.
- Obligations of operators. To ensure an effective joint responsibility, there is the need to define at a legislative level the responsibilities of Food Business Operators (FBO) and to differentiate them from the regulatory authorities and other actors of the value chain. Given that an FBO is best placed to devise an appropriate system for supplying safe food/feed, it holds primary legal responsibility for ensuring compliance, in particular with food safety requirements.
- Participation of developing countries in meetings. Officials in QI institutions whose mandate is food safety should be involved in consultative SPS forums. A country should have the capacity to participate, coordinate and follow up on relevant meetings and activities of regional and international organizations including WOAH, the Codex Alimentarius Commission, the WTO SPS Committee and regional economic communities. Legislation should consider these international forums as part of the authority mandate, within the limits of the entity's legal mandate.
- Prioritization framework for SPS capacity building planning. The SPS capacity building needs of a country can vary and should therefore be ranked according to priorities. These should be established based on, but not limited to, domestic public health, costs and trade impacts, local environmental protection and impacts on productivity and poverty. SPS assessments and construction of action plans consider sector specific and cross-cutting issues. This plan that should be adopted by policy or legislation, should also consider existing QI capabilities and QI development to avoid duplication of capacities.

6.2.2.

SECTOR SPECIFIC TECHNICAL REGULATION GAPS AND GOOD PRACTICES BASED ON PROPER USE OF QI.

The following sector specific gaps and good practices should be considered:

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
Lack of coordination of relevant QI actors and competent SPS authorities can create SPS procedural obstacles such as lengthy procedures, arbitrary requirements and multiple inspections by different institutions.	The roles and responsibilities of NSB and the responsible authorities should be clearly defined in policy and/or legislation. Awareness should be raised on the elements of the NQI. The complementarities between regulators and QI services should be explored at the country level to achieve food safety. Dialogue between SPS management agencies should be enhanced and legally sanctioned to facilitate trade.

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
The effective implementaion of SPS is constrained due to **weak capacities of national coordination bodies as well as insufficient scientific capacity** (know-how and infrastructure for SPS activities) to set and enforce SPS measures and to analyze risk. Most laboratories are not internationally accredited. There is low awareness of the private sector of SPS measures and insufficient capacities to meet standards.	Improved access to information on SPS requirements and procedures can ensure compliance in addition to the creation of transparent and simplified documentary requirements and procedures for SPS controls. Adequate and accredited laboratory capacity (at a national or regional level) and availability of resources should be facilitated to promote mutual recognition and reduce redundant SPS controls. Good practice recommendations and materials should be developed related to implementation modalities of SPS measures.
There is a **lack of robust QI services** including, but not limited to, accreditation of CABs, efficient traceability and accuracy in laboratory testing and insufficient involvement of private actors. For example, seafood products may frequently test negative for specific bacterial contamination in their country of origin, only to yield positive results upon arrival in the destination country.	To be internationally recognized, mandatory (e.g. HACCP) and voluntary certification (e.g. Eco-label) schemes should be based on internationally recognized standards; **hence, third-party certification** should be adopted. Enhancing the traceability, accuracy and consistency of testing is crucial, in conjunction with the development of related reference material related to biology/microbiology. Many developing countries continue to rely on imported certified reference materials for microbiological tests. Therefore, the strategic implementation of metrology and RMP biology holds significant importance for many developing countries.
The lack of harmonization of the technical basis of standards and regulation can negatively affect businesses, as they find themselves navigating through multiple agencies. Specifically for the spice supply chain, with production spanning both developed and underdeveloped regions, the need for international harmonization of technical standards and food regulations is a particularly pressing need. Further, the high levels of microbial contamination in spices and residues of agrochemicals (for examples, pesticides), environmental contaminants (like dioxins), heavy metals and PAHs and deliberate contaminants (such as dyes) points to the need for enhanced regulatory oversight throughout production and processing.	A robust NQP plays an important role in ensuring the harmonization and effective implementation of QI systems as well as improving the coordination and involvement of both public and private institutions in trade facilitation. NQP should take into account the interests of ministries that rely on food regulations for the implementation of their own policies. Additionally, it should also consult with relevant stakeholders. With particular reference to the spice sector, technical guidance documents published by ASTA on analytical methods, adulteration and contamination prevention, microbial safety, and cleanliness specifications, together with the General Guidelines for Good Agricultural Practices published by IOSTA, are useful tools to harmonize the technical basis of technical standards and food regulations. ASTA conducts interlaboratory testing, which is useful for assessing the proficiency of spice testing laboratories.

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
Competent authorities do not consider that longer and more fragmented supply chains, such as the fishery supply chain, are more prone to **deficiencies in the integrated implementation of HACCP principles**. Additionally, in many countries, regulators implement distinct certification schemes for farms/vessels, traders/distributors and processors, and focus mainly on downstream certification.	Given the mandatory nature of HACCP in many countries, within the food sector, including the fishery sector, it is relevant to establish robust HACCP certification schemes encompassing the entirety of the supply chain, from upstream to downstream levels. As government institutions may not have the capacity or resources to control the whole supply chain, the engagement of private, accredited CABs in the process is necessary.
Credibility of regulatory framework and official SPS measures and role of food safety competent authority in inspection procedures.	Accredit own inspection services or use accredited third-party inspection bodies.

6.3. COSMETICS

Trade organization agreements provide some of the most important legal and institutional mechanisms for countries to take advantage of and benefit from international markets. This is especially important in dynamic, high value-added and sustained growth environments such as the cosmetics market, which in 2021 reached a global size of over USD 380 billion.

Apart from variations in their definition as found in the different national legislations, it is understood that cosmetics are products intended to be applied on body surfaces and that they have effects on these surfaces. Cosmetic producing countries therefore seek to satisfy the national and international demand for this product type, which is characterized by a hyper-segmented supply with the lowest possible health risks without affecting the life, health, or integrity of people, and with minimal impact on the environment.

Another element that contributes to the complexity of the sector has to do with countries' objective to protect their consumers by using their own sovereignty to ensure the necessary measures to reduce the human health risks from imported and nationally produced cosmetics, and to discourage misleading commercial practices while avoiding the introduction of unnecessary trade barriers. This delicate balance is not easy to maintain and only possible with a specific legal framework that does not limit innovation, and with a robust QI.

Cosmetic products often have to comply with legislation that differs greatly from country to country. In addition, as it is an industry with very high added value, apart from safety and protection issues, there are other aspects that, driven by the speed of innovation, are beyond the scope of existing legislation and require that the industry must make greater efforts in self-regulation[77] and in complying with market-driven private standards.

In this sense, **market-driven private standards** developed by societies or industry associations such as Cosmetics Europe and the Personal Care Product Councilprovide accepted benchmarks for setting technical and performance technical standards for products. Growing concern for health

[77]Initiatives by the value chains themselves to incorporate globally accepted good practices that generate market-driven standards, e.g., codes of ethics for advertising and advertisements of cosmetic products.

and the environment has prompted the use of ethical labels and the adoption of sustainability, ecological, natural and/or organic or responsibility market-driven private standards, which seek to ensure quality, reduction of environmental and social impacts, non-use of animals, and use of products free of toxic substances, among other things. Examples include the Cosmos Natural seal, which guarantees that products with this certification comply with high sustainability market-driven standards in aspects such as manufacturing, organic agriculture, chemical contaminants, and packaging. Often the parties who issue them need to be accredited under product certification schemes such as ISO/IEC 17065:2012.

Similarly, innovation and changing consumption patterns require that health agencies and national authorities, as well as conformity assessment service providers, continuously update their capabilities to ensure economic welfare and low health risk. This is particularly challenging considering that these types of entities have greater restrictions to adopt rapid changes due to their legal frameworks and budget, technical and technological limitations. In these cases, a well-developed and adaptable QI is of great help to governments and the private sector.

6.3.1

SECTOR SPECIFIC KEY CONSIDERATIONS ON TECHNICAL REGULATIONS AND HOW QI WOULD BE OF USE.

In addition to the general cross-cutting considerations presented in the introduction to Chapter 8, the following sector specific considerations must be taken into account for the cosmetic sector:

» **Regulatory** approaches **are not harmonized** between countries, making it difficult to bring the same product into all markets. This is true, for instance, of product classification, which depends on ingredients, labelling and intended use. Under this approach, the same product may be classified as a cosmetic in one country, and as a special cosmetic or as a drug in another, implying significant differences in the approval/registration, control, and surveillance processes. This is the case of sunscreens, which in both the EU and Japan are considered cosmetics, while in the US are considered over-the-counter drugs, a category for which monographs have been published as additional regulatory instruments. As safety is one of the principles that strongly guide the regulation of cosmetics, additional requirements have recently been created (such as those in the EU). These include the safety assessment that must be performed, as well as additional responsibilities such as the post-marketing follow-up of possible undesirable effects of cosmetics, to avoid their recurrence or reduce their consequences, which must be reported to the health authorities.

» At the international level, there are initiatives such as the International Cooperation in Cosmetics Regulation (ICCR) that address issues aimed at recognizing the different legal regimes of markets (the EU, the US, and Asia) and discuss **opportunities for harmonization**. Ultimately, because these are voluntary initiatives, differences in terms of classifications, authorizations, and prior/posterior control prevail in the main regulatory frameworks of reference. For example, in addition to the general conditions for **"consumer protection"** (see 8.1.1), the use of positive and negative lists of ingredients for use in cosmetics is common in the different legislations; however, while the US restricts the use of fewer than 20 chemical substances, the EU restricts the use of more than 1400 hazardous chemicals. Similarly, the US only has negative lists; thus, there are differences in categorization, approvals and notifications, use of claims, packaging and necessary testing, among other things.

» Two other arenas for addressing issues that, while not strictly regulatory, are of high importance as they influence harmonization processes are the Organization for Economic Cooperation and Development (OECD), which promotes mutual acceptance of data, and the International Organization for Standardization (ISO), which establishes international technical standards for test methods and good manufacturing practices.

» An additional important issue in the evaluation of cosmetics is **animal testing**, which due to its ethical and environmental implications is being banned in the EU and in some states of the US and Brazil. However, some countries do not recognize the validity of alternative tests, as is the case of Canada, China and Japan, where animal testing may even be mandatory for certain product categories. This leads to a technical barrier to trade, as products tested on animals for markets such as China cannot enter markets such as the EU or vice versa. Although this topic is in the early stages of scientific and technological development, several roadmaps have recently been developed for different national agencies (e.g., US EPA, EFSA) to support the implementation of new approach methodologies for a replacement of animal testing for chemicals when possible. Furthermore, the International Cooperation on Alternative Test Methods (ICATM) was

created to foster dialog among national validation organizations. This dialog facilitates international cooperation in the critical areas of validation studies, independent peer review, and development of harmonized recommendations. The development of technical standards in this field will be important to unify criteria and to address the current lack of harmonization.

» Cosmetic product packaging often has features that seek to identify the products as luxury goods. To avoid the use of misleading packaging due to these features, some **legal metrology** legislations include specific requirements for cosmetic products based on recommendations issued by OIML. Others may include prescriptions linked to the variation over time of the net content in certain categories such as cosmetic soaps, provided they are duly supported by reliable studies. Another important aspect to consider is that, given the chemical nature of cosmetic products, countries have a legitimate interest in regulating aspects that may have an impact on **environmental protection**. Thus, issues such as biodegradability and the restriction of the use of hazardous substances are subject to regulation, as well as registration, the safe management of chemical substances and the disposal and use of waste and packaging. In some cases, ISO standards can propose methods or procedures to be considered in regulations.

» In general, the adoption of technical regulations for cosmetic products includes elements of protection of legitimate interests through non-tariff measures (WTO/TBT) and health risk reduction (WTO/SPS). QI facilitates mutual recognition between countries of conformity assessment with respect to such measures, but the levels of approval or acceptance will depend on the health risk assessment made by each country. In any case, it is advisable to use technical standards for the development of technical regulations, as well as accredited conformity evaluation so as not to create technical barriers to trade. The more QI is used, the smaller the differences between regulations will be.

6.3.2

SECTOR SPECIFIC TECHNICAL REGULATION GAPS AND GOOD PRACTICES BASED ON PROPER USE OF QI

The following sector specific gaps and good practices must be considered:

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
Lack of sanitary and regulatory harmonization between economies leads to duplication, longer lead times and high costs for cosmetics producers and ultimately for consumers.	Adopt GRPs that include the definition of technical requirements based on widely recognized international technical standards and the establishment of conformity assessment schemes based on the risk-based approach. **ISO Technical Standards for cosmetics**: Cosmetics are being standardized within the framework of ISO Technical Committee 217, which has developed technical standards for test methods, packaging and labelling, technical definitions and criteria for natural and organic cosmetic ingredients and products, and guidelines for GMPs. A good practice is to use these ISO technical standards as a basis for developing technical regulations.

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
The low availability of sensory, safety, stability, and efficacy testing, as well as non-clinical studies for a wide range of cosmetics products can pose challenges in demonstrating compliance with technical regulations and fulfilling cosmetic product registration requirements, especially in developing countries.	An adequate QI will allow producers in countries with insufficient technical testing capabilities to rely on the internationally recognized accreditation of CABs under the premise **"tested once, accepted everywhere"**. In addition, quality systems for the international recognition of non-clinical studies are often available as a tool for registering cosmetic products prior to their commercialization. This is the case for the **OECD Good Laboratory Practices,** which, through the mutual acceptance of data (MAD), avoid duplication of studies in cosmetics and other chemical products in more than 40 countries. According to OECD data, the savings to government and industry through MAD are around 309 million euros per year. In some countries, NABs have a recognized function of granting recognition to laboratories under the OECD GLP scheme. Where applicable, results issued by these recognized laboratories should be accepted for compliance obligations.
Many of the requirements established in technical regulations are related to the measurement of parameters, limits, or other physicochemical characteristics. The nature of cosmetics as specialized chemistry products may limit the supply of reference materials of active ingredients, excipients, preservatives, perfumes, and colorants necessary for such measurements, thus affecting the ability of producers to demonstrate regulatory compliance.	National metrology institutes can boost the supply of reference materials through various mechanisms including direct production, the provision of measurement services and the transfer of technology and knowledge to other levels of the metrological pyramid. Accreditation also provides schemes for recognizing producers of reference materials other than NMIs, positively impacting not only regulatory compliance, but also research and development in the cosmetics sector. A good practice is for regulators to promote the production of reference materials to support compliance with established requirements.

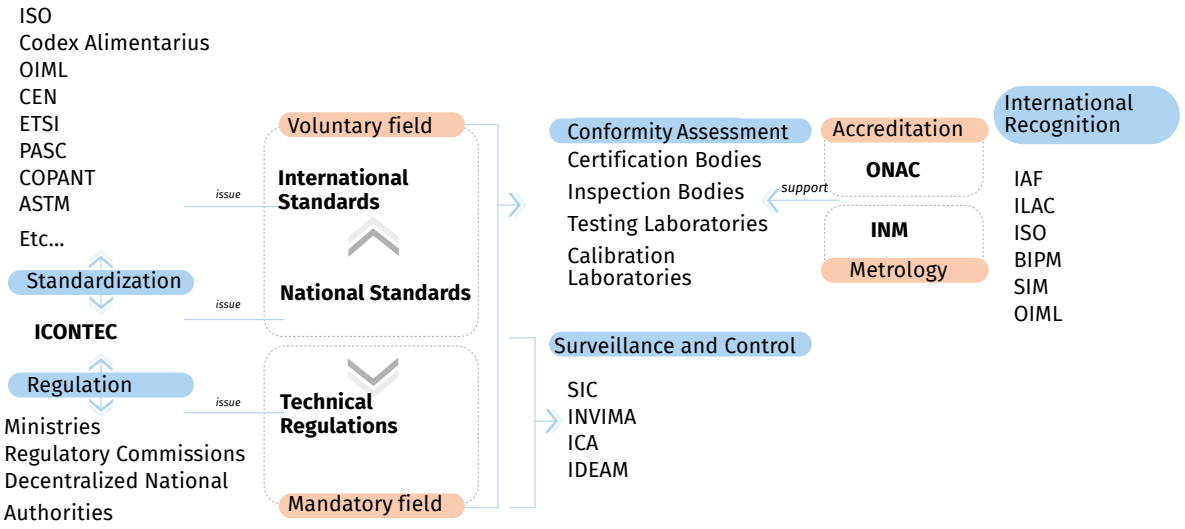
CASE STUDY: QUALITY INFRASTRUCTURE AND COSMETICS REGULATION IN COLOMBIA

The National Quality Subsystem (SICAL) is the term used to describe Colombia's QI system. Established in 2006 based on a national policy, SICAL has defined its actors and functions over time. The Superintendency of Industry and Commerce (SIC), which previously oversaw most QI activities, divided SICAL's functions. It retained oversight of technical regulations and authority over the country's legal metrology, while its national metrology institute (INM) was established to oversee scientific and industrial metrology. Additionally, the Colombian National Accreditation Body (ONAC) was established to manage accreditation.

Through Decree 1595 of 2015, ONAC was also tasked with monitoring OECD good laboratory practices, while the standardization function remained under the ICONTEC (Colombian NSB). This same decree

stipulates that the Ministry of Commerce, Industry, and Tourism is responsible for coordinating SICAL and for the technical secretariat of the Intersectoral Quality Commission, an instance that links the different QI actors mainly for technical regulation purposes. Apart from the QI pillars of standardization, accreditation, and metrology, SICAL includes ministries and regulatory entities, as well as market surveillance agencies and institutions in various sectors. Examples include the Superintendency of Industry and Commerce as well as the Colombian Agricultural Institute (ICA) for phytosanitary matters, and the National Institute for Food and Drug Surveillance (INVIMA) as the country's health agency. Finally, conformity assessment bodies that provide quality services are also part of the subsystem.

General Scheme of SICAL stakeholders. Adapted from Decree 1595/2015



In Colombia, the entity responsible for overseeing production and good manufacturing practices in the cosmetic sector is INVIMA. Through Resolution 2108 of 2020 and Resolution 2206 of 2021, INVIMA grants a production permit (mandatory) to cosmetic manufacturers prior to commercialization, known as the "Certificate of Production Capacity." This certificate confirms compliance with technical, locational, hygienic, sanitary, staffing, and human resource conditions by the cosmetic product manufacturing industry, ensuring its proper functioning, as well as the technical capability and quality of its products.

Furthermore, according to Resolution 2214 of 2021, INVIMA can certify companies in GMPs with a validity of five years for those who voluntarily seek recognition of this certification with countries belonging to the Andean Community (Bolivia, Colombia, Peru, and Ecuador).

Internationally, the ISO 22716:2007 standard is recognized, which applies to the manufacturing, control, and storage of cosmetic products. Certification with this standard is granted by recognized certifying bodies, and some of its guidelines are recognized as mandatory compliance requirements in legislations of Europe, the US, and Japan. Additionally, efficacy, stability, and homogeneity tests can be conducted by cosmetic manufacturers using accredited conformity assessment laboratories.

There is no incompatibility between the requirements requested by both models (INVIMA's GMPs and ISO 22716:2007), although there are differences in the way some of these requirements are detailed. The most important difference is that INVIMA does not act as a CAB but as a health authority. Moreover, each standard has specific additional requirements not covered in the other. In 2018, INVIMA became an observer member of the ICCR with the support of UNIDO.

The core institutions of the SICAL have also developed public goods and services that support compliance with regulations and voluntary standards in the cosmetics sector. The National Standards Institute, ICONTEC, has technical standardization committees for cosmetics and sensory analysis. The national metrology institute has recently developed reference materials for heavy metal analysis in lipstick, and the Superintendency of Industry and Commerce has included specific requirements for soaps and cosmetics in the latest updates to the national regulations for prepackaged products.

6.4
AUTOMOTIVE

The automotive industry is a significant contributor to the global economy; its worldwide market size was USD 2,738,387.98 million in 2021 and is projected to reach USD 3,577,110.64 million by 2031[78]. The resulting economic geography of the industry is complex, with only some segments being fully global. Inter-regional vehicle and parts trade is substantial but capped by political and operational considerations. Intra-regional trade of finished vehicles and parts is the dominant operational pattern. Domestic production is still very strong in many national markets. Activities such as design or assembly tend to be geographically concentrated in clusters within countries[79]

Due to the high degree of standardization for its processes and products (including raw materials, auto components, and assembled sets), the automotive industry can incorporate auto parts from different origins into a single vehicle. These rigorous rules are based on international standards, on private standards such as those of the International Automotive Task Force (IATF), on national regulations, and on requirements included in international agreements such as the 1958 United Nations Agreement. This relies on the availability of sufficient internationally traceable measurement systems, harmonized certification schemes, and recognized CABs, including testing and calibration laboratories that can issue certificates and other evidence recognized either globally or in target markets.

The automotive industry's commitment to adhering to globally harmonized technical regulations covers safety, comfort, energy efficiency, natural resource usage, air pollution, and fair-trade practices throughout a product's lifecycle. This reflects the characteristics of an international manufacturing ecosystem that pioneers operational excellence tools and production management techniques, continuously improving productivity and ensuring product quality.

The universal perspective of the industry promotes standardization in most operational aspects. This has led to the establishment of the IATF as one of the primary entities in coordinating the efforts of a large group of automakers and their respective automotive industry associations to provide high-quality and safe products. IATF's main tool is the IATF 16949:2016 standard, which integrates the various evaluation and certification systems from each automotive brand's supply chain around the ISO 9001 standard on quality management systems.

When technical regulations are enforced that specify performance requirements for vehicles, components, or subsystems , vehicle and spare part manufacturers update the standards and other guidelines (for example, in the form of private requirements, drawings, or private technical guidelines), or process parameters of certification systems such as IATF 16949, along its value chain. This yields a comprehensive and systematic research and development process for the production of safer and cleaner vehicles.

Whether vehicles and spare parts are produced domestically or imported, legal frameworks apply regulatory practices whose aim is to contribute to legitimate objectives. This is achieved by avoiding any unnecessary requirements for trading, by partaking in international agreements or, if not possible, by adopting GRPs including impact analysis methods, use of international standards, acceptance of conformity assessment procedures, and implementation of market surveillance strategies.

Legal frameworks also establish a conformity assessment procedure for goods prior to their introduction into the market, based on the concept of type approvals; depending on the given case, such approvals can be issued by a third party, through a first party declaration, or verified directly by the relevant authority. In all instances, this procedure involves testing laboratories in private (first party), independent (third party), or official (road safety authority) facilities. Moreover, regulators often perform market surveillance processes directly or through third parties to ensure compliance in production processes and to prevent non-compliant products.

[78] Business research insights (2024), Automotive market report overview. Available at: https://www.businessresearchinsights.com/market-reports/automotive-market-102183#:~:text=The%20global%20automotive%20market%20size,comprises%20various%20companies%20and%20organizations.

[79] OECD (2010), The automobile industry in and beyond the crisis. Available at: https://www.oecd.org/economy/outlook/44089863.pdf

Due to the highly diverse types of production processes and products (steel, metal, plastics and rubbers, textile, chemical, services, etc.), the automotive sector can be considered a cross-industry. Thus, sectorial development policies and legal decisions, including regulations, are often used as a reference by other manufacturing sectors (aerospace vehicle manufacturing, shipbuilding, home appliance manufacturing, etc.).

Furthermore, the prioritization of regulations must consider the root causes of road casualties and international experience. Each country has its own road and traffic conditions; thus, when deciding which performance attribute of vehicles and spare parts to regulate, it is important to gather evidence of the local conditions and safety data and use them to learn from international experience.

In addition, the automotive sector is a good example of an instance in which regulators must avoid requesting or limiting technology by over regulating performance. A definition of a product attribute instead of a performance specification is a pitfall because it limits the development of technical and technological alternatives to mitigate perceived risks and impacts. For instance, it is preferable to regulate the braking performance (braking distance) instead of requiring an ABS (anti-block system) or disc braking systems.

Often, the implementation of technical regulations is linked to QI strengthening, incentivizing the growth and sustainability of CABs, especially when they are related to testing laboratories, management systems certification bodies, or inspection services. The supply chain and the QI that supports the sector reduce dependence on small-scale local markets. The application of a global view also facilitates the involvement of the private sector and the promotion of foreign direct investment in QI.

The regulators must also take into consideration the impact on industrial development, assessing the risks and opportunities of being part of global value chains (GVCs). Therefore, if a country has the intention of becoming an international player in the automotive sector, it must strengthen its QI, including technical assistance services for SMEs, to the point that it can sustain the stringent conditions required to enter, remain, and grow within the GVCs. Each country's automotive industry has different traits including production features, the availability of incentives for development, enforced trade agreements, the level of access to technology, the existing productive capacity, the road conditions, and even the stability of the legal framework that regulates the sector.

It is important to highlight that technical regulations can be a component of sector-specific action plans that are aligned with the country's sustainability goals. Such regulations may include technological vehicle upgrades, an energy transition, road safety improvements, new mobility alternatives, mass transport, industrial development and infrastructure, industry 4.0 concepts, commercial diversification, investment attraction, and circular economy.

6.4.1

SECTOR SPECIFIC KEY CONSIDERATIONS ON TECHNICAL REGULATIONS AND HOW QI WOULD BE OF USE

The automotive sector requires regulations with a holistic approach that address a diverse number of conditions derived from the markets of new and used vehicles, spare parts and service supplies. Some key considerations for technical regulations in this industry include:

» **Harmonization of the regulatory framework with international best practices** The main international technical reference document for vehicles, the 1958 United Nations Agreement, established the conditions to facilitate the trade of vehicles and their parts among signatories. Over time, the Agreement has evolved, updating its priorities while preserving its initial commercial benefits and ultimately becoming a global technical regulatory framework that addresses safety, environmental, energy and technological challenges for vehicles. This framework has fostered a scenario of global participation and representation and now includes several Addenda that are referred to in the agreement as "regulations", as they are mandatory for signatory countries. The regulations contained in the Addenda to the Agreement establish harmonized technical standards dealing with performance requirements, approval and market surveillance procedures, and criteria for new vehicles, spare parts, and systems; they also consider conditions for regular inspections of in-use vehicles. As an international instrument, the 1958 United Nations Agreement still needs to comply with local legal requirements for adoption and ratification.

  The signatories to the Agreement are beneficiaries of substantial contributions to the fulfillment of sustainability commitments, to the commercial diversification of their productive sector, and to access to dedicated international QI.

  Countries who are not signatories to the Agreement can adopt individual Addenda while harmonizing the approval and surveillance schemes contained in the Agreement and accepting conformity assessment certificates issued via standardized methods as a legal demonstration of compliance.

» **The establishment of an effective institutional framework to actualize political commitments, which are often related to road safety, environmental impact, or energy transition, promotes industrial development and fair trade.** Ministries of transport, environment, energy, and even health (as sector regulators) may address these priorities and regulatory needs by using QI services such as testing laboratories, calibration services and CABs to verify compliance with technical regulations. However, to exploit the country's competitive advantages and commercial opportunities, it is essential to guarantee a continuous dialogue with trade and industry portfolios. Legally, a coordination scheme may be required to allow this dialogue to take place among public entities in an orderly fashion.

» **Regulators must be aware that the mechanisms that allow for the proper functioning of a vehicle and its spare parts within the performance limits established by technical regulations are defined by measurable factors like physical and chemical properties**. For example, in braking systems, the braking pads, which are made of composite material, need to able to stop the vehicle effectively while wearing down reasonably. These requirements for friction and wear are translated into essential features of the braking pad, including size, shape, weight, strength, frequency, duration, and hardness. These measurements also define the conditions for production and quality control; to ensure trust, international traceability of measurements is essential. Therefore, considering the relationship between performance and metrology, regulators must encourage dialogue between value chain and quality stakeholders with the aim of understanding the current access of institutions and market actors to the metrology services needed for the enforcement of technical regulations. In most legal systems, the promotion of this type of dialogue will be considered a standard task for government officials.

» **Technical standards that define product and production process performance, as well as evaluation methods and acceptance criteria, support legal conformity evidence.** The automotive value chain is highly standardized, mostly based on international requirements. Taking this feature into account, when defining requirements to be included in technical regulations, it is relevant to engage experts, base technical regulations requirements on these existing standards and consult interested parties to identify the intrinsic conditions of the local and international markets.

» **To ensure the safety and compliance of vehicles and spare parts in the market, various checkpoints and actions are necessary throughout the entry into and presence on the market of these vehicles and parts.** Prior to the launch of a new automotive product in the market, technical regulations generally require an initial demonstration of its conformity. Depending on the case, this demonstration is released either as a first-party declaration or as a third-party certification. Which option to consider depends, on the one hand, on the level of the risk to be managed. The higher the risk, the more suitable the third-party certification is. On the other hand, it also depends on the capability of market surveillance services to identify and manage risks to prevent or restrict the use of the non-compliant products on the market and to ensure that the negative impact to legitimate purposes is eliminated, minimized and managed. Thus, the option of first-party declaration necessitates strong and agile market surveillance services, including access to test facilities, public or private. By contrast, third-party declarations require a developed market of CABs together with public or private independent test facilities.

On an international level, the UN 1958 Agreement is based on a third-party conformity assessment strategy, while the US National Highway Traffic Safety Administration (NHTSA) is based on the acceptance of first-party services.

Along the product's lifecycle in the market, regulators address similar trade-offs when verifying if the vehicles and spare parts produced consistently comply with regulatory requirements. The UN 1958 Agreement mandates that regular Conformity of Production (COP) test procedures be performed by an authorized CAB to evaluate parameters and conditions of manufacturing processes, such as those under the IATF 16949 management system. By contrast, the US scheme primarily relies on self-declaration and the market surveillance service's capacity to test the products (with a potential economic burden on the manufacturer in cases of non-compliance). In any case, both approaches integrate communication channels and procedures to report and address any malfunction or non-compliance.

Regulators must comprehensively assess risks and their degree of criticality considering the state of the conformity demonstration infrastructure and the potential for utilizing mutual recognition of evidence as stipulated in international agreements (i.e. trade) signed by countries as legal evidence to define proper actions for risk management while avoiding unnecessary trade requirements.

6.4.2

SECTOR SPECIFIC TECHNICAL REGULATION GAPS AND GOOD PRACTICES BASED ON PROPER USE OF QI

The following automotive sector gaps and good practices must be considered:

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
Lack of alignment of the legal framework with international references.	Technical regulators must participate in international scenarios to learn and share experiences and lessons that can improve the effectiveness of regulations towards legitimate priorities while avoiding unnecessary requirements, as well as in national technical standard committees to be informed and to inform others about new developments in the sector. Any legal and financial requirements or constraints should be considered beforehand.
Outdated requirements in comparison with international practices.	Regulators must establish a periodic review schedule (e.g., every 5 years) for versions of technical standards, tests, and methods included in local technical regulations. Furthermore, employing a robust quantitative impact analysis of enforced regulations is advisable to confirm the effectiveness of the decision.
Lack of reciprocal recognition of conformity assessment certificates between regional or international markets or countries.	Once legal requirements are met (e.g. UN 1958 Agreement), regulators must adopt in their technical regulations international regulatory schemes such as those of the UN 1958 Agreement and its Addenda; in addition, they may adopt NHTSA Regulations and the Blue Ribbon Scheme to guarantee the use of GRPs and the acceptance of conformity assessment certificates issued abroad.
Lack of testing facilities and services: testing laboratories and other CABs.	By allowing in law the use of MRAs, regulators must encourage either the use of international QI or the creation of local CAB capacities to serve local and regional producers and authorities.
Unnecessary requirements to approve the commercialization of products.	To simplify conformity assessment, authorities may use the term “product family” to group products based on similar features. Furthermore, such requirements may avoid imposing trade restrictions that are neither technical nor causally linked to performance.

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
Use of specifications in technical regulations instead of performance requirements.	When adopting technical regulations, regulators must focus on vehicle and spare part performance to promote the development of several technological alternatives for meeting legitimate purposes. Orientation towards international technical standards that follow the performance focus for technical regulation development will substantially support this effort.

6.5
WOOD

Round wood and wood products in general are globally traded products. Overall, the wood processing industry and, in particular, value-added wood product industries such as furniture, flooring, and building construction, constitute a substantial international business sector that is generally profitable. The wood processing industry has traditionally been a resource- and labor-intensive industry including both local craft-based firms and large industrial volume producers. Products from the wood and processed wood sector can be exported at any of the production/processing stages of the value chain. The global wood products market in 2022 was valued at USD 696.78 billion despite recent trade disputes and changing consumer preferences.

Global trends in the wood processing sector are related to numerous different factors including demand, environmental impact, technology, economically sustainable development, population growth, product and state-driven industry regulations, and efficient use of available resources. Below, some of the emerging trends are briefly discussed:

» More and more solid wood products are likely to be replaced by engineered wood products. This will have a strong influence on the technologies used to process raw materials and the requirements placed on these materials.

» Innovative products include lightweight panels for the growing ready-to-assemble (RTA) furniture market and wood composite materials with improved properties due to the combination of different inputs. They offer a huge potential for research and development

and will compete with pure wood products in the future.

- Agricultural residues, bamboo, and other fast-growing plants will become more sought after for the production of panels and beams, thereby replacing wood-based materials.
- Shortages in numerous well-known and internationally traded wood species will promote the testing of lesser-known wood species and their introduction into the international markets.
- Plantation wood will replace ever larger quantities of roundwood from natural forests. This will have an influence on the wood processing sector in terms of wood properties and qualities.
- The fast-growing construction sector will consume larger volumes of wood- and wood-based products, causing an increased demand for engineering of new products.
- Technology and quality requirements for wood- and wood-based products will increase because the general improvement in living conditions will lead to higher standards and regulations.
- The indispensable need to manage global forests in a more sustainable manner and a stricter implementation of binding regulations such as the European Timber Regulation and the US Lacey Act may strengthen the position of international certification systems such as the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC), especially in countries which face challenges for practicing sustainable forest management.
    - Demand for wood fuel will continue to increase due to population growth (mainly in Asia and Africa), as well as the shift from fossil and nuclear power to green energies (mainly in EU-countries).
    - The concept of the circular economy is gaining importance in public policies, and its approach influences and promotes both the responsible production of wood and the responsible consumption of wood and wood replacement products.

Wood products are defined by a large number of international and national standards. Normally, the relevance of standards increases the more value is added (e.g., increasing degree of processing). In low value-added primary products, the main purpose of standards is to help buyers and sellers agree on the physical dimensions, volumes, grades and ultimately the prices of their primary goods. However, in some important markets like the EU and the US, standards support producers to fulfill strict rules on the legality and of certification schemes, including for primary wood products.

For high value-added wood products for sale to customers, the role of standards becomes more oriented towards fitness for purpose and consumer safety. This is where good practices in manufacturing, testing of strength and durability, and issues related to flammability and toxic emissions of substances like formaldehyde come into play. All these tests require accredited, well-functioning laboratories to acquire the certificates needed to be able to sell a given product on the global markets.

Wood exporters to the EU market should consider existing EU regulations. Regulation (EU) No 305/2011 of the European Parliament and of the Council laying down conditions for the marketing of construction products. It provides a definition of harmonized conditions for the marketing of construction products, including timber and timber products. Regulation (EU) No 305/2011 is valid for all members of the EU as well as the ECAC (European Economic Area Countries). Countries like Ukraine have adapted this regulation into its legislation by adopting it into national law. Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 lays down the obligations of operators who place timber and timber products on the market. The Timber Regulation is designed to counter illegally harvested timber and timber products. The Regulation covers a wide range of timber products listed in its Annex using EU Customs Code Nomenclature. The defined timber products include solid wood products, flooring, plywood, pulp and paper. Not included are recycled products, as well as printed papers such as books, magazines and newspapers.

Several technical regulations regulate furniture products. While customers generally decide on aesthetic, functional, and quality aspects, technical regulations address safety as a key criterion. For example, the European general product safety directive emphasizes the importance of this issue by indicating that responsibility for product safety lies with the company placing the product on the market. The market itself is the competence of the individual countries. The European Commission maintains a rapid alert system for dangerous non-food products; dangerous furniture products are routinely referred to in this system alongside other products. Windows, doors and façades are covered by the European Construction Products Regulation. For windows and external pedestrian doors as well as for curtain walling (façades), harmonized product standards are applicable. The CE mark is mandatory for these products when placing them on the market, which makes it necessary to test and declare certain characteristics such as air permeability and water tightness.

One relevant piece of documentation is the list of reasons for common border rejections (in the EU), which include:

- General or quantitative import restrictions for specific wood products
- Insufficient proof of the legality of wood products
- Non-fulfillment of international agreements/ conventions
- Non-fulfillment of required technical regulations
- Non-fulfillment of required phytosanitary regulations (e.g., vermin)
- Falsely declared products (e.g., in order to save taxes)

Globally, there are more than 50 private certification programs which pertain to the forestry and wood processing sectors. The two most important international certification programs in this area are FSC and the PEFC. Globally, about 440 million ha of forest (19.7% of the total global forested area) are certified by FSC or PEFC. Certified forests produce certified lumber and wood fiber that may be further processed and sold on the market.

In order for a labelled wood product to be sold to a client, it is compulsory for all actors along the production process to also be certified according to the same system. Chain of Custody Certification (CoC) tracks the certified material through the entire production process from the forest to consumers, including all successive stages of processing, transformation, manufacturing, and distribution. It provides evidence that certified material in a certified product originates from certified forests. About 33,000 wood processing companies around the world have a CoC certification from FSC or PEFC. Certification for both FSC and PEFC is not requested by the competent authorities, and the majority of the certified forests and the wood processing companies are located in the northern hemisphere.

6.5.1

SECTOR SPECIFIC KEY CONSIDERATIONS ON TECHNICAL REGULATIONS AND HOW QI WOULD BE OF USE

Some specific sector considerations are:

» **Product Safety:** Technical regulations in the wood sector often focus on ensuring the safety of wood-based products. These regulations may encompass requirements for structural integrity, fire resistance, toxicity levels, and durability. QI supports these regulations by providing international technical standards and recognized testing and certification services to verify compliance, ensuring that wood products meet the defined safety requirements. There are several technical standards which cover the material properties of wood and wood products. With regard to emissions, for example, there are testing standards frequently used to assess carcinogen agents such as formaldehyde, which is often present in adhesives used in the wood industry, such as ISO 16000 Indoor Air Pollution, EN 717-1 Formaldehyde Emissions, and EN 13986 Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking.

» **Environmental Impact:** Sustainability is a central concern in the wood industry. Technical regulations frequently address environmental considerations such as responsible forestry practices, emissions standards for wood processing facilities, and restrictions on the use of certain chemicals in wood treatment. Technical regulations that address these issues should be based on existing international technical standards (ISO 3129:2019 Wood — Sampling methods and general requirements for physical and mechanical testing of small clear wood specimens, ISO 8965:2022 Logging industry). QI facilitates compliance with these technical regulations by offering measurement and conformity assessment tools to evaluate environmental impacts and sustainability practices in the sector.

» **Traceability and Labeling:** Many wood products are subject to technical regulations related to traceability and labeling. This includes requirements to track the origin of wood materials to prevent illegal logging and promote responsible sourcing. Technical regulations that address these issues should be based on existing international technical standards. Nevertheless, the standards used most frequently to this end are private standards such as PEFC and FSC. QI can assist by providing verification and certification services to ensure that wood products are labeled accurately and in compliance with traceability technical regulations. Furthermore, accredited certification bodies can provide certification services and training in the requirements of PSC or PEFC certification. For the latter, it must be ensured that conflicts of interest are avoided so independence of certification services is not compromised by other services provided.

6.5.2

SECTOR SPECIFIC TECHNICAL REGULATION GAPS AND GOOD PRACTICES BASED ON PROPER USE OF QI

The following sector specific gaps and good practices must be considered:

TECHNICAL REGULATION GAPS	GOOD PRACTICES BASED ON QI
Enforcing wood manufacturing regulations, especially those pertaining to sourcing and sustainability, **can pose significant challenges**. Manufacturers often depend on certifications and audits to verify compliance, though the reliability of these programs may fluctuate. Non-compliance carries the potential for substantial penalties and damage to a manufacturer's reputation, underscoring the critical importance of a diligent approach to compliance.	When defining wood manufacturing related technical regulations, the competent authorities should base them on international technical standards to define the performance requirements as well as conformity assessment procedures needed to avoid duplication with those required in foreign markets. QI supports the implementation of certification systems and traceability mechanisms. Through QI-assured certification bodies, wood products can be certified for sustainable sourcing and adherence to environmental and social standards. This helps meet consumer demand for eco-friendly and responsibly sourced wood products.
Emerging technologies. As the industry embraces innovations like engineered wood products and new wood treatment methods, regulations struggle to keep pace. There is a need for updated technical regulations to ensure the safety and performance of these new materials.	QI institutions are also a tool for research and development to evaluate the safety and performance of emerging technologies related to wood. QI can help identify potential risks and benefits, contributing to the formulation of updated technical regulations that accommodate innovation while ensuring product safety and quality.

CASE STUDY: UKRAINE'S APPROACH TOWARDS ADAPTATION OF THE NATIONAL LEGISLATION TO EU REQUIREMENTS

The government of Ukraine is actively working on Ukraine's integration into associative accession to the EU. As part of this process, work is underway to adapt national legislation to EU requirements, which will allow integration into the European market.

UNIDO has been supporting this adaptation process in Ukraine to allow wooden window manufacturers and relevant laboratories to use European approaches for product testing, which will provide them access to European markets.

These standards will become mandatory as they will be included in the list of standards in accordance with the Ukrainian law "On the provision of construction products on the market", which was implemented in accordance with Regulation (EU) 305/2011.

Through this process, cooperation with the Ukrainian Association of Window Systems as the main member of the specialized technical standardization committee has been established. Thanks to the active work of this association together with the National Standardization Body, 18 European standards have been officially adopted.

7 CONCLUSIONS AND CLOSING REMARKS

In principle, there is a need for dialogue among QI actors, legal actors and policy makers. This guide offers a good basis to initiate and facilitate a fruitful, meaningful, informed and adequate dialogue among QI actors, legal actors, and policy makers.

It also shows that coordination between the responsible individual entities of the QI, including the QI pillars, the conformity assessment bodies and calibration laboratories, is indispensable for a balanced and effective development and use of QI in knowledge-based society.

Also, it must be emphasized that the three QI pillars, namely standardization, accreditation and metrology, must be considered public goods because they are accessible to everyone, their use does not prevent others from using them, and they benefit society as a whole by improving consumer confidence, facilitating trade, and promoting sustainable development. However, prohibitive costs of accessing them can undermine their role as public goods.

Therefore, it is important to base legal reforms on a previously designed and adopted quality policy and to understand and consider the following.

» The interrelation of QI with a wide range of different rules of law, society, and QI-sustainable economic megatrends is related for the most part to the achievement of SDGs.

» QI needs to support activities from different actors, both private and public (policy makers, regulators, etc.), and must simultaneously operate within and further productive, service-oriented, regulated, development oriented, scientific, monitoring, and innovative environments.

» To operate as a supporting system, QI must ensure the competence, impartiality, independence, neutrality, and non-discrimination towards third parties of its own actors.

» QI has the opportunity and need to integrate and benefit from different international, regional, and global institutional and legal conventions, technical agreements and other settings (such as cooperation between members).

» To be sustainable, QI requires a demand-driven approach to the development and provision of QI services be continuously considered.

To tackle these important challenges, a legal framework is needed to structure QI and QI services at a local or regional level as necessary. This includes, among other legal issues, the legal structuring of a QI central coordination arrangement, QI pillar institutions, their financing arrangements, the acceptance of conformity assessment bodies and calibration results in the country and from abroad, among other essential elements described in this document.

At the institutional level, several structures are needed at the local or regional level. A central QI coordination body in the country should be established to coordinate QI and state actions and to consider the proper use of instrumental international trade and technical agreements to allow national QI to be deployed and maintain, as needed by each country, and ensure equal treatment of national and foreign QI service providers.

To ensure the needed QI institutional setting, specific legal considerations need to be taken into account. The list of specific legal issues for each of the QI component seem to be very long, but each of them need to be considered to ensure a functional QI. In this guide, specific legal considerations have been elaborated bearing in mind the diverse situations of the given economies, their geographic locations and legal histories when implementing and strengthening their QI legal policies and rules.

A NSB should be established bearing in mind the need for legal standing of technical standards; the definition of a national standards body as a legal entity; the determination of the NSB's governance; the establishment of financial provisions of the NSB, if needed; the adoption of the main administrative provisions of the NSB; the institutionalization of the NSB's formal system for openness and transparency; the definition of how technical committees should be set up and structured; the adoption of a technical standards setting process; the determination of the relationship between the NSB and other technical standard development organizations; and the adoption of rules for the external relations and recognition of the NSB.

An NMI should be established taking into consideration the legal standing of measurement units and national measurement standards; the national metrology institute (NMI) as a legal entity; the NMI's governance; the financial and main administrative provisions of the NMI; the NMI's laboratory management and measurement recognition; the potential designated institutes (national metrological reference laboratories); and the external relations and recognition of the NMI.

An AB should be established contemplating the legal standing of accreditation; the legal standing of the national accreditation body; the governance of the AB; the financial and main administrative provisions of the AB; the AB's accreditation process; and the external relations and recognition of the AB.

In addition, in relation to conformity assessment and calibration services, the legal system should consider the legal standing of conformity

assessment and calibration services; the legal entity of conformity assessment bodies and calibration laboratories; the protection and support to accredited services; the CAB's and calibration laboratory's accreditation process; the formalities to designate the CAB; and the registration of trained auditors.

It also has been made clear that, when the legal and technical dialogue involves policymakers and regulators, there are important aspects to be considered. Legal considerations by sectoral authorities for the use of QI, must include, in general:

- Active participation in the formulation / elaboration and implementation of the national quality policy and legislation
- Self-restraint and coordination with other policies and authorities
- Active participation in advisory / governance boards of QI institutions
- Active participation in standardization technical committees and use of national and international technical standards
- The utilization of measurement units and metrological traceability;
- The use of accredited CABs
- The need to give conformity assessment results their proper evidentiary place in the legal system

Finally, as QI services may efficiently and effectively support different types of state regulations, specific considerations should be contemplated when making use of this possibility and fostering international and regional regulatory cooperation. The model examples in the automotive, food, wood and cosmetic sectors presented and discussed in this guide show how regulations benefit from QI services, supporting the application of a risk-based approach without overreaching and affecting other uses of QI locally.

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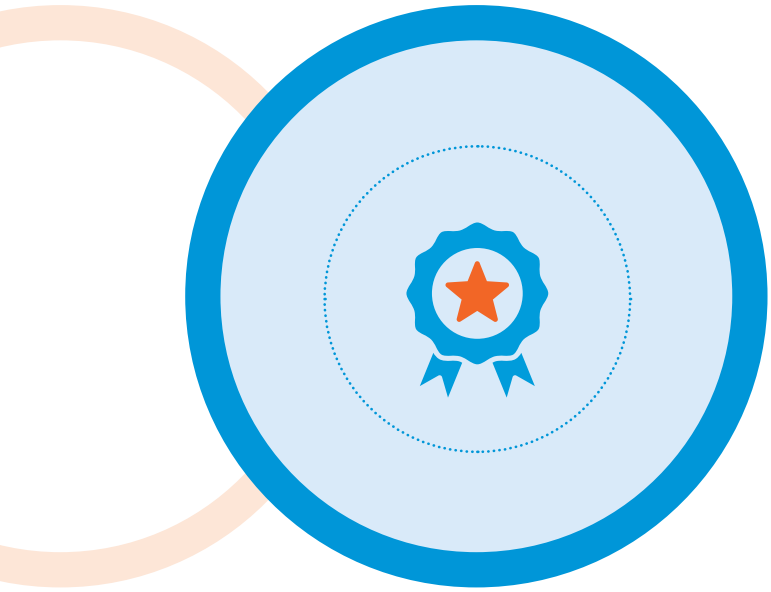
ANNEXES



ANNEX 1:

SPECIFIC LEGAL CONSIDERATIONS: STANDARDIZATION

The local and/ or regional systems to set technical standards need to follow particular best practices in order to fulfill their potential.

1.

LEGAL STANDING OF TECHNICAL STANDARDS

Compliance with technical standards is not inherently legally binding, unless a contract between parties or a technical regulation or other legislation makes it mandatory.[80] Nonetheless, adhering to technical standards is a best practice that allows tenders, contracts, transactions, and concessions among private actors, and between private actors and public institutions, to operate more efficiently. It is also a best practice for technical regulations to reference technical specifications defined in existing technical standards. Consequently, technical standards find legal application when there is a need to agree or regulate the design, use, quality or performance of materials, products, process, services, systems, and persons.

It is recommended that the legal framework should allow at least the following technical standards referencing methods in their text and other legal documents:

i. Direct references to specific technical standards in the legal text;
   a. Direct dated references;
   b. Direct undated references (when the national or regional legal system allows it); and
ii. Indirect references to specific technical standards in the legal text.

The national technical standards must have legal standing or a legal framework within the legal system of the country to underline their special nature and practical applications, even though they are not seen as per se legally binding, as the baseline for any specification to be used or mandated in the country. They play a critical role in domestic markets and are significant within the context of the WTO TBT Agreement, which also presents in its Annex 3 the Code of Good Practice for the Preparation, Adoption, and Application of Standards.

To comply with the WTO TBT Agreement, the NSB is required to use international technical standards, where they exist or where their completion is imminent, as a basis for national technical standards except where such international technical standards would be ineffective or inappropriate, e.g., country specificities of the product (good), insufficient level of protection, fundamental climatic or geographical factors, or fundamental technological problems.[81] This assessment should be carried out internally by the NSB and supported by the use of ISO/IEC Guide 21 to indicate the extent to which national technical standards are adoptions of international technical standards (i.e., identical, modified, or not identical). The identification of international or regional technical standards development needs to be followed by national "mirror committees" from among the usual list of technical committees.

2.

THE NATIONAL STANDARDS BODY AS A LEGAL ENTITY

The NSB must be established as a legal entity, enabling it to be held legally responsible for its

[80] A custom that is still being practiced in some parts of the world, where the older system of compulsory standards is used instead of the system that differentiates technical standards from technical regulations.

[81] WTO (1995), TBT Agreement. Article 2.4.

technical standards development and publication activities. Although it is not recommended, the NSB may be defined as a part of a legal entity. However, the most effective and efficient approach is to set up the NSB as a statutory body or private not-for-profit organization.

In all events, the legal provisions should allow a government authority to designate the NSB as the country's representative at the IGQNs concerned with standardization. These legal provisions must be incorporated into legislation or, if feasible, in the internal by-laws of the organization, depending on the legal nature of the NSB.

3.

NSB GOVERNANCE

The governance structure of the NSB must be well-defined in its primary legislation or by-laws, ensuring the establishment of an independent board or council with fiduciary responsibilities. This governing body should consist of members from the public and private sectors with knowledge regarding standardization and market dynamics.

The NSB and its council or board must have a statutory mandate or a mandate in its by-laws to effectively manage the affairs of the NSB without undue outside interference or restrictions. For the governance of the NSB, issues of independence, non-conflict of interest and financing need to be considered beforehand and drafted into primary legislation. Best practice indicates that the private sector must be well represented in the board or council of the NSB.

The NSB and its board or council must be allowed by primary legislation or its by-laws to decide on the following:

1. adoption and revocation of technical standards
2. determination of staffing and positions within the organization
3. appointment of the Director/CEO of the NSB and the corresponding job specification
4. setting the salaries of its workforce
5. creation of new administrative divisions
6. establishing its own budget
7. deciding on fees of technical standards publications
8. offering new services or initiating new activities
9. seeking membership in international or regional standardizing organizations and signing international agreements
10. adoption of the NSB formal system
11. commissioning, decommissioning or modifying any of the NSB technical committees

Additionally, the legislation should allow government authorities to designate an NSB as the country's representative at the GQNs concerned with standardization.

It is essential to consider certain technical reasons for maintaining a sole body for standardization to prevent dilution of technical requirements due to competition. If a private body also operates as a legal or *de facto* monopoly, primary legislation must establish pricing and governance rules to prevent abuse of its dominant position. In any case, smart rules need to be in place so that the NSB is allowed to enter other markets, such as providing conformity assessment services or consultancy services, while preventing abuse of its dominant position.

In primary legislation or in the by-laws, the designation and responsibilities of a director or CEO for managing the NSB's day-to-day affairs should be clearly outlined. It should also be taken into consideration that the director or CEO of the NSB is designated by and accountable to the board or council. It is recommended that the director or CEO of the NSB must be a member of the board or council of the NSB. Additionally, the director or CEO of the NSB must act as the legal representative of the NSB as defined in a legal act or the by-laws of the organization. Internal rules should define key performance criteria for the director or CEO, and evaluations should be conducted at least annually by the board or council.

Furthermore, as defined by internal rules of the NSB, the head of the technical standards department should be a full member of the NSB's executive management.

4.

FINANCIAL PROVISIONS OF THE NSB

The NSB must be allowed by primary law or its by-laws to receive funding or grants from various sources, including the government or any other entity or entities, for the development of national technical standards. To ensure the NSB's financial sustainability in the medium to long term, it should have access to funds from sales of technical standards and information, financial support from

industry, and other sources, following general central budget rules or applicable regulations. It is of high importance for the NSB to be legally authorized keep any income received from other activities and to hold up reserves for future investments. In case the NSB is not able to receive funding from the sources or grants mentioned above, the state must ensure the sustainable financing and thus the required functioning of the NSB. To supplement any or all the income required by the NSB, the NSB's director and its line ministry should earmark sufficient grants to meet international and regional commitments of the NSB and support the NSB's standards setting process and information center. The law for its part should ensure that no restrictions are imposed on international payments and dotations to allow international technical cooperation to operate with no difficulties.

Consideration should be given to the nature of the QI core institutions when formulating the NSB's financial provisions. In many legal systems, fees for public entities are typically set and defined by primary or secondary legislation, as appropriate.[82]

In general, the standard act or the NSBs by-laws must allow (and not restrict unnecessarily) the entity to lease or own adequate premises, invest, and maintain necessary technical equipment, and to implement a quality management system. The NSB, as a premier QI organization, among others, must be legally allowed to:

» occupy adequate premises to perform its mission. Notably, it must have meeting rooms for technical committee meetings and a technical standards information center easily accessible and invitingly organized (i.e., not far away from the entrance or in a poorly maintained, dark, and uninviting place); and

» have an effective and efficient intranet and internet presence available with properly maintained IT equipment (servers, computers, printers, digital projectors, electronic communication and so on). An up-to-date website containing all relevant NSB technical standards and other documents is also highly desirable.

Finally, but equally important, the NSB should be legally allowed by primary law or its by-laws to defray these expenditures to achieve the objectives indicated above.

[82] It should be noted that, when private NSBs receive government subventions, they may be subject to certain legislation dealing with public funds audits; they may also be deemed to have public administrative functions and might have to comply with general or specific administrative procedures.

5.

MAIN ADMINISTRATIVE PROVISIONS OF THE NSB

Most countries have general acts that deal with issues of public or private employment, as well as other administrative issues. Depending on the legal nature of the NSB and the country's legal system, civil service or general labor provisions need to be applied to the NSB.

To ensure effective management, personnel with the necessary skill sets, qualifications, and experience should be appointed, supported by relevant training. Internal management rules must formally define the responsibilities of the NSB. The establishment of internal key performance indicators (KPIs) defined and evaluated at least annually by the board or council for management and internal personnel is highly desirable. In some legal systems, primary law may be used to consider a more expedited procedure to fill any managerial and technical posts within the organization.

Secondary law or the by-laws of the organization must allow for the set-up of the NSB's organizational structure that optimally supports the technical standards development process consisting of:

» technical standards development

» technical standards editing, approval, and publication

» technical standards information and sales

» In addition, the NSB must have clearly identifiable and separate departments for:

» project approval (can be management)

» technical standards development

» editing

» technical standards information and sales

» national WTO TBT Enquiry Point[83]

With the adoption of the TBT Agreement in 1995, the long-standing practice sanctioned by the GATT's Standards Code (1980) is no longer possible, and countries need to consider technical standards as voluntary and technical regulations as mandatory. This separation is essential to resolve issues of confidentiality, avoid any potential conflict of interests with any commercial services provided by the NSB, and ensure the integrity of the standardization process. If, despite the best practices recommendations, the NSB remains involved in the development and/or implementation of technical regulations (including those technical regulations enacted as mandatory or compulsory standards),

[83] WTO (1995), TBT Agreement. Article 10.1.

special provisions must be included in primary legislation to separate as clearly as possible the functions of standardization from those of technical regulations (including those technical regulations enacted as mandatory or compulsory standards).

6.

NSB FORMAL SYSTEM

The board or council must be allowed by secondary law or the by-laws of the entity to adopt a formal system for the NSB, considering the rules for consultation and transparency during the technical standards setting process. In particular, the formal system must allow for:

- wide circulation of technical standards drafts for public comment for at least 60 days, as prescribed by Annex 3 of the WTO TBT Agreement. This public consultation period should occur after the technical committees have completed their deliberations and before they are presented for approval and publication
- circulation of technical standards drafts to the general public through the NSB's website as well as by targeting important stakeholders such as authorities and business associations individually
- compilation of all comments by the secretariat and submission to the technical committee for consideration
- invitation by the technical committee to entities making substantive comments to discuss issues in person
- once the draft of the national standard has been approved, publishing it (in hard copies or electronically) in the shortest time possible

7.

TECHNICAL COMMITTEES

Technical committees' processes must be managed effectively and efficiently by the NSB secretariat. This includes the existence and adherence to well-defined committee work programs, holding meetings at appropriate intervals, promptly circulating meeting minutes, and providing complete documentation in a timely manner for participants to allow them to prepare properly for meetings. To ensure a systematic approach, the management of technical committees must include internal rules to have a formal system in place. Such rules include requiring each of the technical committees or work groups to have a formal work program, a committee meetings schedule, a policy to record the minutes of the meetings, and a guideline to create documentation in a format that facilitates the discussion on technical requirements.

NSBs must be allowed to provide appropriate training, either in-house or externally, for technical committee chairpersons, secretariats, and technical standards information personnel. Keeping records of these trainings is essential to ensuring consistently high quality in the technical standards development process.

Technical Committees, Sub-Committees and Working Groups should ideally be composed of fixed experts. However, new technical experts should be welcomed at any time and their members' motivation to participate should be based on the genuine interest to participate and be updated in their knowledge through group discussion.

Additionally, the NSB must have internal rules to conduct formal annual evaluations of personnel based on agreed-upon key performance criteria. These evaluations will help determine the effectiveness and efficiency of the personnel involved in standardization activities and identify their future training needs.

8.

TECHNICAL STANDARDS SETTING PROCESS

The NSB must be granted authority to develop internal policies, procedures, and work instructions for technical standards development while ensuring their public availability. Specifically, the following provisions should be incorporated into secondary law or internal rules:

- A work program for technical standards projects must be developed and updated continuously as new projects are approved. This work program for voluntary national technical standards must not be confused with the program to prepare and adopt technical regulations, as they are two separate programs.
- A publicly available "standard for a standard", should be internally developed, validly approved, and used by all technical committees and the NSB as the guiding document for technical standards development. This document must cover all of WTO TBT Annex 3 requirements.
- A complete set of internal procedures and work instructions aligning with ISO 9001 documentation requirements must be

developed, implemented, and maintained for the entire technical standards development process.

» An editing manual must be developed and implemented to ensure the consistency and quality of published technical standards.

Technical standards are to be developed by technical committees (including subcommittees and working groups) representative of interested parties (e.g., ministries, public authorities, business, industry, consumers, academia, and civil society) as established by the internal rules of the NSB. Technical committees are to be:

» established based on a needs analysis

» not limited to a specific number of participants

» open to all interested parties approved by the council or board

Best practice indicates that representation in technical committees must be balanced. The NSB must strive to achieve this goal and be formally inscribed in the "standard for a standard". The NSB should continuously identify stakeholders, engage in clear communicate with them, and secure their support and participation in the development and implementation of national, regional, and international technical standards. While collecting sales and trend information for future planning, the NSB should be mindful of local data protection legislation.

Primary or secondary law must define the NSB's ability to print national technical standards and charge for them. The NSB must have a technical standards information service able to provide information on national, regional, and international technical standards to interested parties in hard copy and electronically. Therefore, legal rules must allow the NSB to set up a fully functional technical standards information center based on a modern IT system, if possible (including online sales and credit card payments), and established with full information on the following:

» national technical standards

» technical standards of selected trading partners

» regional technical standards

» relevant international technical standards

9.

TECHNICAL STANDARDS DEVELOPMENT ORGANIZATIONS

Technical Standards Development Organizations (SDOs) can play a supportive role in the NSB's work by developing technical standards that are subsequently published as sectoral or national technical standards by the NSB. To facilitate this collaboration, primary technical standards legislation or the NSB's by-laws may consider a mechanism allowing the NSB to formally recognize SDOs, such as ministries, professional societies, and academic institutions compliant with international and regional obligations, to also develop national technical standards. The NSB must be able to formally evaluate compliance of SDOs with international and regional obligations such as Annex 3 of the WTO TBT Agreement before recognizing them and must coordinate the work programs of SDOs with its own every six months.

10.

EXTERNAL RELATIONS AND RECOGNITION OF THE NSB

The NSB pays a crucial role in a country's international technical and trade relations, representing the country internationally vis-à-vis other technical standards setting bodies and taking a substantial part in the WTO TBT Inquiry Point development and operation.

The NSB must have the legal (as expressly permitted by primary law or the entity's by-laws) and financial capacity to be able to secure the appropriate level of membership of subregional, regional, and international standardizing organizations relevant to the country (e.g., ISO, IEC, CAC) and to be actively engaged in their technical standards development activities.

To ensure international participation, an NSB board or council must also have the legal power (in primary law or the entity's by-laws) to approve the strategy for the involvement of international standardizing organizations, including active participation in their technical committees.

Regarding the adoption of regional technical standards, the primary legislation must consider the necessary provisions to enable NSBs to adopt approved regional technical standards in accordance with regional directives, protocols, or legislation. In some common markets, regional technical standards must be adopted (with no

variations) at the national level within a specified period (e.g., six months), and national technical standards of a similar scope must be withdrawn. If this is the case, this type of adoption needs to be considered in primary legislation.

The WTO TBT Inquiry Point for the country should be well-equipped to provide information to WTO member states. This includes technical regulations implemented by all regulatory authorities, technical standards utilized in all technical regulations, conformity assessment regimes for technical standards and technical regulations, and international and regional cooperation agreements regarding conformity assessment.

The WTO Inquiry Point must have legal and financial support to collate comments on WTO TBT mortifications for later consideration by the relevant ministry and for forwarding them to the country's Geneva WTO representative. The NSB or other designated authority may undertake the task of the WTO Inquiry Point. If the NSB has been designated as the WTO TBT Inquiry Point, a formal designation is required by the ministry responsible for trade. This can be done via primary legislation or a formal delegation document by the responsible authority. The WTO must be notified of this fact by the country's trade representative.

In addition, it is recommended for the WTO TBT Inquiry Point to establish an early warning system through secondary legislation. Information about technical regulations should be provided to exporters; before sending any feedback to the country's NSB, feedback must be received from exporters. This system should serve as an "early warning" mechanism. This early warning can be provided directly by the WTO TBT inquiry point or made accessible through the NSB website.

ANNEX 2:

SPECIFIC LEGAL CONSIDERATIONS: METROLOGY

For structured and detailed information on the Law on Metrology and its relationship to the legal QI framework, please refer to OIML Guide (D-1)[84], BIPM-OIML publications on national metrology systems *Developing the institutional and legislative framework*, 2021[85],the International Vocabulary of Terms in Metrology (VIM)[86] and the International Vocabulary of Terms in Legal Metrology (VIML).[87]

The following texts supplement or reinforce the above-mentioned documents.

1. ACTORS AND ROLES IN METROLOGY

Metrology legislation needs to define and consider the different roles the following authorities play in metrology:

- Central government authority[88]
- National metrology institute (NMI)
- National legal metrology authorities
- Local legal metrology authorities
- Private sector providers of metrology services to industry and to the economy
- Structures for disseminating knowledge and competencies in metrology (e.g. training, education, etc.)
- Coordination and cooperation in the metrological infrastructure

2. LEGAL STANDING OF MEASUREMENT UNITS AND NATIONAL MEASUREMENT STANDARDS

To ensure metrological traceability to the International System of Units (SI) and international compatibility, a system of national measurement standards and reference materials must be established and formally adopted through primary law. The responsibility for these tasks should be entrusted to an institution designated by governmental decision to act as the national metrology institute (NMI) or its equivalent.[89]

Legally, national measurement standards (which include reference materials from this point on) must be most commonly adopted by secondary legislation [90], offering legal certainty through appropriate legislation. These measurement standards should be defined by legislation based on the International System of Units (SI) as well as any locally used customary measurement units. Additionally, they should be listed in an official government publication, in primary or secondary legislation as allowed by the local legal system. To ensure their preeminent position, national measurement standards should take precedence over other measurement equipment within the country, including those used for legal metrology and regulatory inspection or testing equipment.

[84] OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf
[85] Idem
[86] OIML (2007) OIML V 2-200 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), Edition 2007 (E/F) Available at: https://www.bipm.org/documents/20126/54295284/VIM4_CD_210111c.pdf
[87] OIML (2022) International Vocabulary of Legal Metrology (VIML) – Digital Edition 2022 Available at: http://viml.oiml.info/en/index.html

[88] As indicated by OIML in D-1:2020 (en), at the center of a national metrology infrastructure, there should be an authority in the government in charge of the national metrology policy, and of coordinating the actions of other parts of the government related to metrological issues. This can be arranged in a number of ways by the government.
[89] OIML (2022) International Vocabulary of Legal Metrology (VIML) – Digital Edition 2022 Available at: http://viml.oiml.info/en/index.html
[90] Idem

The units of measurements with legal standing should encompass the following and may be included in primary or secondary legislation, as required:[91]

» units of the "International System of Units" (SI), adopted by the General Conference on Weights and Measures and recommended by the OIML for legal purposes

» units used for quantities that are not covered by the SI, as specified by a decree of the government

» customary units as decided by the government, which may include specific units for special application, required by the necessities of international trade, for specific uses such as air or maritime navigation, health care, or military applications, or for safety reasons[92]

It is advised that the use of units other than legal units should not be allowed in trade, commercial transactions, documentation and advertisements for products and services, publications, or training, with the following exceptions: [93]

» documentation of and references to products produced and services carried out prior to the obligation of the units concerned

» mentioning non-legal units in a historical perspective in publications and training

» documents and publications intended for users in countries that have different systems of units

In addition, as part of its roles in the Metrology Act, the NMI (or the designated institutes or national reference laboratories appointed by the NMI) must be allowed specifically to establish:

» national measurement standards that are appropriate for the demonstrable needs of the country

» national measurement standards to provide a high-level and metrologically traceable calibration service as indicated by the country's needs

» national measurement standards and reference measurement standards appropriately maintained and calibrated to ensure their full functionality

Finally, measurement and calibration results may be used as legal evidence for judicial and administrative cases. They may be used as a legal and valid evidence before a court of law or vis-à-vis administrative authorities with specific regulatory functions. Some QI legislation provides rules related to what evidentiary weight they should have for these authorities - i.e., if the judge or magistrate must make notice of them (for primary calibrations) or if they are to be considered as prima facie evidence of the results obtained (for secondary calibrations).

[91] Idem
[92] Idem
[93] Idem

3.

THE NATIONAL METROLOGY INSTITUTE (NMI) AS A LEGAL ENTITY

A national metrology institute (NMI) must exist as a legal entity vested with the responsibility of developing and maintaining national measurement standards and disseminating the SI units.[94] Due to the nature of the services it needs to provide to assist all relevant stakeholders, the NMI's legal entity should preferably be a technical or scientific institute, rather than just a mere authority.

Typically, successful NMIs operate as independent, and well-funded public institutes.[95] Today, NMIs in industrialized countries serve as the national focus of measurement science, providing leadership to nationwide and worldwide scientific cooperation relating to metrology.[96] However, in some economies, the NMI's functions are not restricted to a single entity. Also, some countries have a distributed system where several different metrology institutes develop and maintain national measurement standards in their own specialized fields and work collectively, coordinated by one institute that functions as the country's NMI. Nonetheless, as explained below, for sound economic reasons, the NMIs of most countries are public bodies. Nevertheless, in the event that the NMI is not a public entity, its by-laws must consider, as required the following legal elements.

Ideally, the NMI must have the legal capacity, normally in primary law, to:[97]

[94] PTB and WB (2019), Quality Infrastructure Rapid Diagnostic Tool, 2019. Available at: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/docs/QI_Toolkit/PTB_Info_QI_Rapid_Diagnostic_Tool_User_Guide_EN.pdf
[95] See OIML D-1 (2020) (en), Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

An NMI may have various possible structures:

- a public institute owning and running its own laboratories
- a private institute owning and running its own laboratories under the authority of the government, considering issues of unfair competition and national security
- a public agency coordinating public or private institutes

[96] OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf
[97] Idem

- establish metrological traceability to the SI, depending on the quantity, either by realizing the definition of the unit or by keeping, maintaining, and continuously improving the national measurement standards that are metrologically traceable to the SI via a foreign institute
- disseminate the measurement units, which involves providing metrological traceability to the national references for calibration laboratories – that is, the provision of calibration services either to a national network of (typically commercial) calibration laboratories, or in the smallest economies, directly to the users in industry and elsewhere
- engage in related international activities, e.g., comparisons
- ensure the international recognition of calibrations (and thus tests) to avoid technical barriers to trade through participation at regional and international levels in the international recognition systems operated by BIPM and/or ILAC12
- carry out development work on the improvement of national references
- where possible, undertake research activities to prepare for the next generation of metrology measurement standards
- provide the necessary advice and support to the government, industry, commerce and the public on metrological issues
- provide a sound metrological basis for the national accreditation scheme, including the provision of experts for assessments
- provide expertise through national, regional or international measurement standard developing organizations (i.e., for documentary measurement standards) to ensure appropriate treatment of measurement issues.

In cases where a core NMI function is left to a private body, primary or secondary legislation should be clear on whether the NMI must face competition or be regulated. In any scenario, the NMI must not be allowed to compete with secondary calibration laboratories or to overcharge for its services. In addition, depending on the case, other provisions such as a limitation to enter other markets may be desirable for certain institutional frameworks.

4.
NMI GOVERNANCE

Traditionally, NMIs have nearly always been entirely within the public sector. In general, an NMI requires rules for a proper governance structure in primary or secondary legislation to ensure an adequate administration and independence. In some countries, more recent policies have attempted to give NMIs a degree of management autonomy that is appropriate for the efficient and effective running of a research-based organization with services to the public. [98]

Primary metrology legislation should consider the possibility for the NMI to have a metrology advisory board or council with advisory functions consisting of members from the public and private sectors with specific knowledge regarding metrology and market realities. Also, the private sector should be represented in the board or council. In this respect, the election, functions, dismissal, operation and office terms of the Board/Council of the NMI and its members need to be considered.[99]

Without prejudice to any ministerial policymaking functions, in primary or secondary metrology legislation, as the case may be, the NMI and its board or council must have the mandate to effectively manage the affairs of the NMI without undue outside interference or restrictions to: [100]

1. decide which measurement standards are the national measurement standards
2. officially designate other institutions to be custodians of national measurement standards
3. determine the positions and staffing of its workforce
4. determine the salaries of its workforce
5. determine its own budget and income quantitatively
6. create new administrative divisions
7. offer new services or initiate new activities
8. solicit membership in international or regional metrology organizations and sign international agreements
9. adopt and follow up on a metrology strategy that will result in the implementation of the QP regarding scientific and industrial metrology

In an instance where the NMI has no council or board, the designated Central Government Authority for metrology may take up the first two functions presented above. The others may need to be defined considering each country's legal system. This will most likely need to take place in primary

[98] PTB and WB (2019), Quality Infrastructure Rapid Diagnostic Tool, 2019. Available at: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/docs/QI_Toolkit/PTB_Info_QI_Rapid_Diagnostic_Tool_User_Guide_EN.pdf See also OIML D-1: 2020 (en).
[99] Idem
[100] Idem

law. In this case, the definition of new services and international memberships must be left to the NMI, unless primary legislation is required for the adoption of an international convention, such as the Metre and OIML Conventions. In these two cases, Parliament or Congress / National Assembly will need to approve them first and Governments will need to adhere to them.

Primary legislation should acknowledge the need for a director or CEO who is vested with well-defined responsibilities for overseeing day-to-day NMI operations. It should also consider that the director or CEO of the NMI is designated by and accountable to the board or council. If the legal system does not allow it, actual legislation should consider the appointment by the central government authority considering the profession, competences and knowledge. Serving as the legal representative of the NMI, the director or CEO requires stipulated roles and annual evaluation of key performance metrics by the board or council or some other equivalent system.

Furthermore, the NMI must remain impartial when obtaining and supporting calibration and measurement capabilities (CMCs), and when supplying calibrations. It is advisable to include impartiality rules in primary legislation. In addition, confidentiality rules need to adhere to by the NMI when performing its roles. These confidentiality requirements must also be considered in primary legislation.

In conclusion, the NMI needs to be recognized by primary legislation as the most suitable means for government to provide the public with an independent and impartial source of advice about the validity, credibility and reliability of metrological information.

5.

FINANCIAL PROVISIONS OF THE NMI

Special attention must be paid to the sustainability of the NMI. Therefore, appropriate financial resources must be provided for their long-term stability. This is best achieved when NMI funding respects the following conditions:

» missions of general interest are financed by public funding

» products or services which are in the marketplace do not cause unfair competition

It should be considered that reference metrology entrusted to the NMI is generally not financially sustainable on its own. Since it is generally difficult to collect fees from the use of measurements, NMI functions are generally considered to be a public good in economic terms. For this reason, the NMIs are normally public entities and receive government grants or subventions (such as the central budget, special public sector or science and technology programs), donations, international cooperation or private project funds, etc. Therefore, public finance rules and the central budget funds need to be committed for the continued existence and adequate operation of the NMI, e.g., by the government or any other entity or entities. Therefore, it is recommended to have a formal financial plan established by the central government authority, with the assistance from the council or board for the medium term, i.e., the following 3–5 years. If the legal system does not allow it, actual legislation should consider that the financial plan must be defined by the central government authority responsible for metrology in a transparent manner.

Revenue from offering training and technical assistance or supplying calibrations to accredited and other laboratories is in most cases insufficient to cover the service costs. When defining fees, some systems require legislation to define a procedure to set any fees by public entities. In addition, most legal systems require that public entities' fees be set up and/or defined by legislation (either primary or secondary). In other cases, only public entities (sometimes extended to appointed private bodies) may need to be allowed by legislation to receive subventions. Furthermore, as indicated above, when a private body is also a monopoly, pricing and good governance rules need to be defined beforehand and adopted via secondary legislation.

To support with this financial need, some countries have opted to partially fund NMIs by allowing them to keep the fees produced by the provision of calibration, training and other services, or to have those funds allocated back to them in the nation's central budget.

In addition, some specific funding for the NMI needs to be earmarked to comply with some international and regional commitments. Governments and other entities have been able do that, for example by creating a special fund. These arrangements would normally need to be included in primary legislation, alongside rules to administer and audit the special fund.

Some governments have sought alternative models, in "distributed" systems where there are organizations with a different ownership or legal status, but where most of the funding is still arranged to come from public sources. This has often required the introduction of more flexible accounting or management processes that are closer to the management models for the private

sector than to those for administrative units in government. [101] It should be noted that public funding distribution is normally made by other legal means such as the central budget for the state.

6.

MAIN ADMINISTRATIVE PROVISIONS OF THE NMI

Most countries have general acts that encompass matters related to employment and civil service, as well as other administrative issues. Depending on the legal nature of the NMI and the country's legal system, specific administrative provisions may need to be included in the metrology primary legislation.

The NMI's management and technical personnel require skill sets and technical competence attainable through proper training, as well as other qualifications, management experience and technical knowledge as necessitated by the various activities of the NMI. Primary legislation must facilitate the continuous employment of trained and experienced metrologists, aligning with the diverse demands of metrology fields and their levels of complexity. To accomplish this, the legal framework must allow for:

» metrologist and other technical posts to be clearly defined and applied

» metrologists and other personnel to gain relevant experience in more advanced NMIs including in legislation secondment provisions

» technical personnel who develop and maintain measuring equipment and environmental controls to be trained and gain experience

Furthermore, the NMI should be empowered to provide training for metrologists engaged in the country's metrology system. In this regard, the NMI must be legally allowed (and no legal restrictions may be included in legislation regarding this) to:

» have a formal in-house training program for its own metrologists or extend training opportunities throughout the national metrology system

» encourage and facilitate advanced training of its metrologists, including opportunities for specialization in emerging metrology fields at NMIs abroad with higher levels of expertise

Additionally, procedures to filling managerial and technical posts must not be overburdening, and internal management rules must formally define the responsibilities and Key Performance Indicators (KPIs) for NMI's management and other technical posts.

Overall, metrology legislation must allow (and not restrict unnecessarily) the NMI to lease or own adequate premises, invest and maintain necessary technical equipment, and to implement a quality management system. The NMI, as a premier QI organization, must be allowed to:

» occupy adequate premises designed or arranged to meet the technical requirements and environmental conditions, to ensure the optimum accuracy levels of metrology activities for each metrology field. Therefore, laboratories, offices, and other buildings need to meet the physical requirements for each of the metrology fields and their accuracy levels

» acquire and maintain equipment, national measurement standards and reference measurement standards for accuracy, as defined by the needs of the country for each of the relevant metrology fields

» establish and maintain effective and efficient intranet and IT equipment (servers, computers, printers, digital projectors, electronic communication, etc). An up-to-date internet presence with a comprehensive website containing all relevant NMI measurement standards and other documents is also highly desirable

Finally, but equally important, the NMI should be allowed by primary law to defray these expenditures to achieve the objectives indicated above.

7.

NMI LABORATORY MANAGEMENT AND MEASUREMENT RECOGNITION

An NMI must have no legal restrictions to prepare and adopt an appropriate quality management system (e.g., ISO/IEC 17025 or similar) formalized through relevant quality system documentation that is not only in place but effectively implemented.

Inter-laboratory or key comparisons are essential elements that validate the NMI's ability to deliver accurate measurement results, forming the foundation for accreditation and the establishment of the NMI's calibration and measurement capabilities (CMCs). To ensure that these vital assessments can be carried out, the NMI must be legally allowed and adequately funded (and no legal restrictions may be included regarding this) to achieve the following aims:

101 OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

participate in inter-laboratory comparisons with other laboratories in the country, region or on an international scale

participate in key comparisons organized by the Regional Metrology Organization (RMO) of its respective region

Moreover, the NMI, as a Member State or Associate, must have its legal mandate outlined in primary legislation to attain international recognition. With this general legal function, the NMI should be able achieve international recognition through participation in the CIPM MRA (listing of its CMCs in the BIPM database). Internal rules must also allow the NMI to have a formal, long-term program in place to continue the establishment of CMCs and their listing in the BIPM KCDB.

The legal provisions governing the NMI must not prevent the entity from having a system in place via which the NMI identifies its stakeholders, communicates clearly with them, and gains their support and participation in the development and maintenance of national measurement standards and the national metrology system. It is important to note that, in some countries, compliance with data protection rules and regulations may be necessary to fulfill these obligations effectively.

As indicated by the OIML/BIPM, accreditation of NMI measurement services is not required by the CIPM MRA, though many NMIs are accredited. The decision to accredit rests with the NMI (or their governing ministries).[102]

8.

DESIGNATED INSTITUTES (NATIONAL METROLOGICAL REFERENCE LABORATORIES)

Technical capacity is seldom found in only one laboratory within a country. Therefore, the country's NMI should possess the legal means to designate or propose the designation of specialized measurement laboratories in the country as designated institutes (DI) for metrological purposes. These are normally different from legally mandated laboratory activities to other authorities. However, their technical capabilities may be used as part of the local metrology dissemination network as technically coordinated by the NMI. The primary metrology law must have a provision allowing NMI to assess other laboratories in the country with regard to their:

» experience and scientific expertise of the assessed laboratory

» the possibility to:

  - provide traceability through calibration services on an equal basis to all customers
  - be custodians of one or more national measurement standards
  - act in ways similar to the NMI in clearly defined metrology areas

» adequate resources and stability in fulfilling their role within the national metrology system

Primary law must allow for a valid legal mechanism for the NMI to recognize -or propose the designation by a defined entral government authority- other laboratories as designated institutes (DIs) to act as custodians of national measurement standards in technologies not covered by the NMI: nuclear technology, metrology in chemistry, etc. The legally defined mechanism must allow the NMI to regulate other relevant issues, such as the possibility for the DI to represent the country vis-à-vis other metrology bodies regionally or internationally. In addition, under the defined mechanism, the NMI must have the legal function to monitor the performance of the DI regarding its activities and CMCs at regular intervals.

9.

EXTERNAL RELATIONS AND RECOGNITION OF THE NMI

Securing international recognition of the NMI's CMCs is a critical element to achieve the country's developmental goals. Therefore, the Metre Convention approbatory act or other valid legislation is needed to allow the country to:

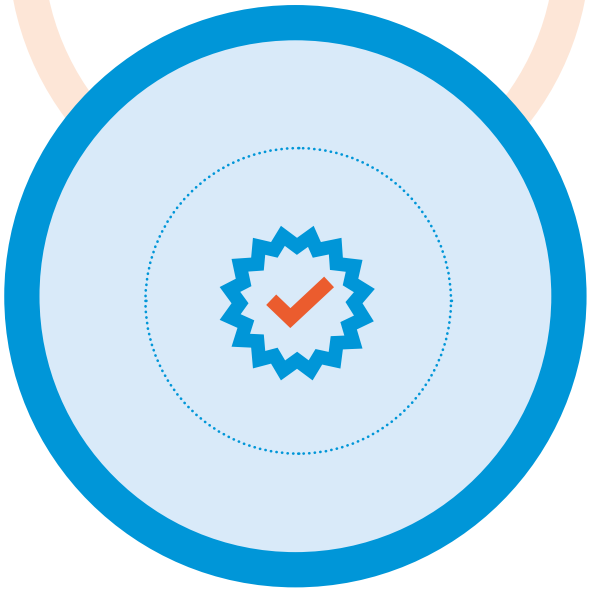
» Participate in the activities of the BIPM either as a state party to the Metre Convention (Member State) or an Associate of the CGPM. NMIs would then have a right to:

  - attend and vote (only Member States can vote) at meetings of the CGPM
  - depending on BIPM membership, attend and vote or merely participate in the CIPM MRA
  - if applicable, participate in relevant CIPM Consultative Committees, etc.

[102] OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

As international work is normally prepared or delivered through metrology regional organizations, the NMI also needs to be accepted as an active member of a RMO recognized by the CIPM. This status is vital to participate in regional inter-laboratory comparisons for establishing the CMCs that form the basis of recognition within the CIPM MRA. Local primary or secondary legislation must allow the NMI to be a full and active member of the relevant CIPM-recognized RMO.

Furthermore, if the NMI is based in a country that is party to a regional trade agreement, it must be an active participant in concomitant regional metrology entities to represent the interests of its country. These regional entities or committees are usually established to harmonize metrology activities within the region defined by the trade agreement and are not the same as the RMOs. Consequently, the NMI must be legally allowed to actively participate in regional trade agreement-related metrology organizations and committees.



ANNEX 3:

SPECIFIC LEGAL CONSIDERATIONS: ACCREDITATION

The local and/or regional systems for the accreditation of conformity assessment bodies and calibration laboratories should consider the following best practices in order to ensure the international recognition of accreditations and reap all of the benefits of internationally accepted conformity assessment and calibration results.

1.

LEGAL STANDING OF ACCREDITATION

The role of accreditation must be clearly articulated in relevant accreditation primary legislation. This delineation should encompass the AB within the realm of technical regulations, the implementation of other legislative instruments, as well as its voluntary use in commercial transactions. These legal provisions must cover the establishment and maintenance of the national accreditation system and the role of the AB in it. Primary legislation must give the AB (whether public or private) an unequivocal mandate by the government to provide accreditation services required in the implementation of technical regulations. In addition, primary legislation must deal with the issue of whether accreditation must be:

- considered the preferred methodology established for demonstrating the technical competence of QI service providers in the country in general
- the legally preferred methodology for demonstrating technical competency in designating QI service providers operating in the field of technical regulations or other regulatory measures utilizing conformity assessment services

The accreditation legal framework must consider the need to coordinate accreditation activities with the other QI institutions in order to ensure fair trade, innovation, trust in products and the operation of market transactions, better goods and services, foreign market access, regulation, the protection of citizens and other societal goals.

Furthermore, primary law shall include a provision to protect the use of the accreditation mark by the AB. Notably, it should be an offence to use the AB's accreditation mark without permission by the AB (i.e. without complying and having passed the required AB's accreditation assessment process.)

2.

LEGAL STANDING OF NATIONAL ACCREDITATION BODY

The establishment and/or designation of an AB is essential to deploy conformity assessment services in the country. As indicated by the standard ISO/IEC 17011:2017(en), the AB must be a legally registered entity, such that it can be held legally responsible and pay for any damages caused regarding its accreditation services. In order to ensure financial solvency, the AB needs to be allowed by primary law or its by-laws to obtain an insurance policy to cover any potential legal liabilities.

There are no limitations for the creation of national accreditation bodies (NABs) or regional accreditation bodies (RABs), but both of them need to comply with the rule to be a legally registered entity.

ABs may be private or public bodies. Therefore, the AB must be a statutory body or a registered legal person in the country. Public ABs are generally statutory bodies, and it is not generally recommended for the AB to be a part of a legal entity, such as a ministry. Private bodies take generally the form of not-for-profit organizations and in some jurisdictions private ABs have the possibility to fulfill some public administrative functions.[103] It is recommended to have not more

[103] In this case, the NAB will generally need to comply and behave as if it was a public entity.

than one AB for each country. If more than one AB is allowed, competition among ABs may lead to situations that potentially affect competence, trust and impartiality. To avoid this situation, the country requires a proven, developed and operational legal system that limits competition among the ABs. However, when an AB stands alone in a country or region, the adoption of checks and balances is required.

QI legislation or the by-laws governing ABs normally define the legal nature, roles and functions of an AB. In all cases, issues of independence and non-conflict of interest and financial provision of an AB need to be considered beforehand.

An AB's primary or secondary legislation, or its articles of incorporation/by-laws must establish:

» a council or board of the AB

» the finances provisions of the AB

» the establishment of the accreditation system

» the AB's designation as the country's international or regional accreditation liaison

As explained in subsection 6.4.iii below, no single entity should perform accreditation roles alongside other incompatible QI functions. Such a scenario would create some legal and technical issues and difficulties that will halt the development of accreditation services and ultimately of the NQI as a whole. Furthermore, it could jeopardize its international recognition.

The primary function of the AB is mainly to accredit conformity assessment bodies. While other activities are generally restricted, there are some exceptions that do not automatically cause the AB to lose its impartiality, such as delivering an open course. Accreditation roles and functions must be considered in legislation or the by-laws as provided by the latest version of standard ISO/IEC 17011:2017(en). Fulfillment of the standard's requirements is needed to ensure the accreditation's international recognition, which is a major benefit for the accreditation services. [104]

ISO/IEC 17011:2017(en) also requires that ABs must not render conformity assessment services provided by conformity assessment bodies (CABs) or consultancy services directly. Training services may be delivered, provided they are legally and practically structured in a manner that does not compromise the impartiality of the AB.

Finally, the identities of the AB's owners or of those with a controlling interest must be either public (in applicable legislation or the AB's public registry) or publicly disclosed (e.g., by indicating the AB members on its official website).

[104] PTB and WB (2019), Quality Infrastructure Rapid Diagnostic Tool, 2019. Available at: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/docs/QI_Toolkit/PTB_Info_QI_Rapid_Diagnostic_Tool_User_Guide_EN.pdf

3.

GOVERNANCE OF THE AB

The legal framework of the AB or the by-laws of the organization must establish an independent board or council as the authoritative governing body of the AB. This board or council must have the mandate to effectively manage the affairs of the AB without undue outside interference or restrictions.[105]

In accordance with ISO/IEC 17011:2017(en) standard, the AB must have a legally defined structure that allows for balanced participation of interested parties in accreditation (with direct and indirect interests) and that one interest must predominate. The board or council must have members from the public and private sector with specific knowledge regarding accreditation and market realities. [106]

Under the AB's legislation or its by-laws, the board or council must have fiduciary responsibilities and the legal power to: [107]

1. appoint and remove the director or CEO and the corresponding job specification
2. prepare and adopt the AB's strategy
3. grant or revoke accreditation (this is fundamental and can also be made by designated accreditation committees)
4. determine the positions and staffing of its workforce
5. determine the salaries of its workforce
6. set accreditation fees
7. determine its own budget
8. create new administrative divisions
9. offer new service or initiate new activities
10. solicit membership in international accreditation organizations and sign international agreements
11. adopt a formal financial plan established for the medium term (3–5 years)

[105] ISO/IEC 17011:2017(en)

[106] PTB and WB (2019), Quality Infrastructure Rapid Diagnostic Tool, 2019. Available at: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/docs/QI_Toolkit/PTB_Info_QI_Rapid_Diagnostic_Tool_User_Guide_EN.pdf

See OIML D-1: 2020 (en): An NMI may have various possible structures:

[107] ISO/IEC 17011:2017(en)

In primary legislation or the by-laws of the organization, a provision should be made for the appointment of a director or CEO, for a certain period of time who may continue for the next term upon successful review by board members, with clearly defined responsibilities for the day-to-day management of the AB. It should be explicitly stated that the director or CEO is designated by the board or council and is directly accountable to it. The director or CEO of the AB must act as the legal representative of the AB and internally, key performance criteria for this role must be defined and evaluated at least annually by the board or council.

ISO/IEC 17011:2017(en) also states that the AB's internal documents must establish an organizational structure that it has a clearly identifiable and separate entity responsible for all the functions. This structure should optimally support the subject fields in which the AB is offering accreditation services, together with the relevant accreditation approvals committee, technical committees, and an advisory committee. The AB's internal rules should lay out different divisions, each responsible for a specific accreditation field, such as calibration laboratories, test laboratories, product certification bodies and management system certification bodies.

Moreover, the AB should be allowed by internal documents or the body's by-laws, and supported by internal decisions, to establish the following structures:

» accreditation approvals committee

» training division

» accreditation advisory forum

Additionally, ISO/IEC 17011:2017(en) states that the AB must be organized and operate in such a manner as to guarantee objectivity and impartiality in its activities. Its services must not be rendered in a biased or discriminatory fashion. Notably, the AB must be able to show formally and in practice impartiality when undertaking its assessments and deciding on granting and revoking an accreditation.

4.

FINANCIAL PROVISIONS OF THE AB

ISO/IEC 17011:2017(en) standard indicates that ABs must have the means to cover all legal liabilities and to adequately undertake its activities. Therefore, government subventions, income from accreditation services, financial support from industry, and other sources (such as government grants or subventions) must be legally accepted by legislation or the AB's by-laws and, adequate to ensure the financial sustainability of the AB in the medium to long term. However, in general, ABs must not have any legal restrictions to comply with applicable financial rules.

Consideration of the nature of the AB is vital when drafting legislation. For example, most legal systems require public entities' fees to be set up and/or defined by primary or secondary legislation as the case may be, whereas private ABs may have more legal and financial flexibility.

All ABs must adhere to general or specific accounting and audit rules, as appropriate. ABs may receive government subventions and in the case that these subventions are recurrent; these funds must be lawfully committed for the continued existence of the AB, as long as they are needed. Also, for these types of Abs, specific funding (from the government or any other entity or entities or special fund) should be earmarked for the international and regional commitments of the AB. It should be noted that, when private ABs receive government subventions, this may be subject to certain legislation dealing with public funds audits; as they could be deemed to exercise public administrative functions, they may have to comply with general or specific administrative procedures.

In situations where a private body is a legal or de facto monopoly, it is crucial to establish pricing and good governance rules in advance to avoid excessive pricing or potential biases. However, if a private body is granted the prerogative to operate with no local competition, preventive rules would need to be in place to ensure that CABs are not overcharged. This can be achieved either by having an authority determining the fees or by setting up a balanced governance structure where the directors of the board may oversee spending and charging of fees. Depending on the case, other provisions such as a limitation to enter other markets may be desirable for certain institutional frameworks.

As a core QI institution for the country, the AB must be legally allowed to occupy premises located in suitable zoning areas that facilitates its mission. These premises must be accessible to customers while providing an environment conducive to maintaining confidentiality, minimizing environmental disruptions, and enabling optimal service delivery. This includes having adequate meeting rooms for technical committee meetings. Moreover, the AB should be housed in facilities that meet legally acceptable working conditions for employees, covering factors such as light, ventilation, temperature, space available, and furniture.

Transparency and openness are fundamental principles for the AB. It must establish and maintain

a transparent system for applications, requirements, assessments, and approval processes related to accreditation, ensuring compliance with ISO/IEC 17011:2017(en) and interpretation documents from ILAC and the IAF. Internal legal documents must consider public and also confidential information.

In addition, in accordance with ISO/IEC 17011:2017(en), the AB must have a formal quality management system implemented. This includes information on accredited organizations being publicly available and up to date (e.g., on the AB website). It is important to highlight that depending on the legal nature of the AB, legislation must consider how to comply with some specific areas of the law, such as the right to petition, constitutional due process principles, habeas data legislation, VAT and other taxes, codes of administrative procedure, public procurement, applicable public archives rules, etc.

Furthermore, the AB must have legal standing to install and maintain an effective and efficient intranet available for its activities, along with proper IT equipment (servers, computers, printers, digital projectors, communication equipment, and so on). This should include measures to ensure confidentiality in line with applicable confidentiality rules as define by primary law. Appropriate presence on the internet, with an up-to-date website containing all relevant AB documentation and details of its accredited companies is also highly desirable and must operate expeditiously. Legal provisions should ensure that there are no unnecessary legal restrictions or administrative burdens on these activities.

The AB should be allowed by primary law and supporting legislation or its by-laws, if needed, to defray these expenditures to achieve the objectives indicated above.

5.

MAIN ADMINISTRATIVE PROVISIONS OF THE AB

Similar to the other QI core institutions, most countries have general acts that deal with issues of employment and civil service, as well as other administrative issues. Depending on the legal nature of the AB and the country's legal system, specific administrative provisions may need to be included into primary legislation.

Management and personnel with the appropriate skill sets ensured by appropriate training, qualifications, and experience for the management and technical knowledge required by the various activities of the AB must be appointed. Additionally, the procedures to fill managerial and technical posts must not be overburdening. Internal management rules must formally define the responsibilities and KPIs for internal personnel. Notably, ABs must not be restrained legally to choose whether their technical staff operates as employees of the organization or as external contractors, unless it is required by the country's laws.

The AB should have the legal authority to hire and have available lead assessors and technical experts for its accreditation services and other related activities. Lead assessors need to be selected, properly trained, and registered (in a formal register) for specific accreditation scopes to lead the assessment teams available. For this, the AB must have a formal set of criteria for the selection and registration of lead assessors that meets ILAC and IAF criteria. The technical competence of lead assessors must also be trained and maintained in line with the established criteria. Furthermore, the AB's registered assessors and technical experts available must also be experienced regarding the specific scope and technology of the organization that is being assessed.

The AB's internal rules should grant it the authority to convene specialized technical committees or working groups comprising experts who can offer valuable guidance on the accreditation process, as well as the training and experience of assessors and technical experts for each accreditation scope. These groups must be established and active for each of the accreditation scopes in which the AB provides services. Specialist technical committees or working groups must be representative of experts from all the stakeholders in both the public and private sector. The AB must consider the recommendations of the specialist committees or working groups and their implementation of these recommendations must be demonstrated. Furthermore, the AB must be legally allowed by its internal rules to have its own formal training system to train lead assessors, assessors, and technical experts, as well as a register of their education, training, and technical and assessment experience.

6.

THE AB ACCREDITATION PROCESS

In legal terms, the process of accreditation is generally a voluntary choice of the CAB and is regulated by a contract executed between the AB and the CAB interested in being assessed and ultimately accredited. As part of the contractual rules, an accreditation process adopted internally by the AB must initiate by an application and includes defined steps such as documentation review, preassessment, assessment team selection, on-site assessment, and exclusion of nonconformities, before an accreditation decision

is made. The formal accreditation process must include the following distinct steps:

» formal application

» preassessment of documentation

» assessment team selection

» on-site assessment

» closeout of non-conformities

Furthermore, as part of the contractual agreements, the process should include specific timeframes for completing each step of the accreditation process, as documented in publicly available materials. With this information, the AB must evaluate its performance concerning the duration of accreditation process steps, report any relevant delays as non-conformities, and take formal corrective action when necessary.

An accreditation approval process, which is separate from the assessment team responsible to grant or revoke accreditation, must be established and operation in accordance with internal rules. The accreditation approvals process must make its decisions guided by formal and well-defined guidelines.

As part of the contractual commitments between the AB and the CAB, an accreditation certificate must be issued to those CABs that have fulfill the accreditation requirement. These certificates must carefully detail the scope of accreditation for a specific duration. Details of the accredited companies should be published, such as on the AB's website or in the publicly accessible database maintained by the AB. When required, as outlined in the guidelines and included in the contract terms, the CAB should be placed on the post-accreditation surveillance and reassessment roster, with audit visits scheduled at intervals in line with international best practices and taking into consideration the stability of the newly established systems, typically occurring at least every six months or annually. Finally, the contract should stipulate that the AB will conduct a complete reassessment of all accreditation elements after a fixed number of years (e.g., three or five years) to extend the accreditation.

ISO/IEC 17011:2017(en) provides certain rules of procedure, including provisions for appealing a negative accreditation decision. In legal terms, disputes over procedural matters are not uncommon. The principle of due process is an internationally accepted and respected legal principle, though the specific aspects of due process are defined by each legal system. Generally, both public and private entities are obligated to respect due process vis-à-vis CABs. However, it should be noted that public entities may be held to a higher standard of due process. This is particularly important in some legal systems. Therefore, it is recommended to incorporate the procedure for accreditation into primary legislation, enabling alignment with international ISO CASCO technical standards and compliance with local due process rules and regulations.

7.

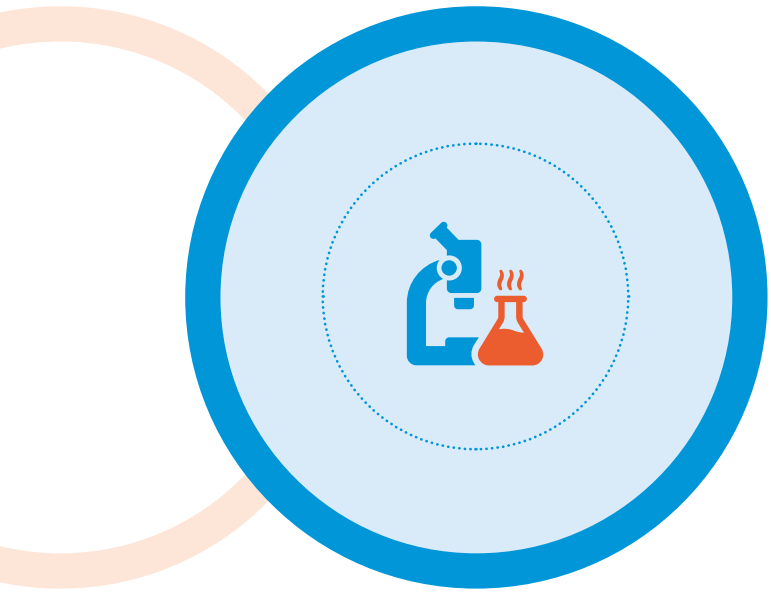
EXTERNAL RELATIONS AND RECOGNITION OF THE AB

The designated AB for the country must, in accordance with legislation or its by-laws, have the legal authority to become a full member or an associated member of ILAC and the IAF. The AB also needs to be actively involved in relevant committees, subcommittees, and information exchange groups of ILAC and the IAF and should be allowed to pay its dues. This participation should extend to attendance at regional and multilateral general assemblies, facilitated either through legal representation or a power-of attorney.

International recognition of the AB is achieved through the establishment of a Multilateral Recognition Arrangement (MLA) with IAF (for certification and validation and certification schemes) or ILAC (for laboratories and inspection schemes). Before signing an MLA, the AB must be legally allowed by legislation or the AB's by-laws to be a member to a regional accreditation cooperation organization and represent the country abroad by executing the necessary agreements.

Furthermore, if the AB is situated in a country party to a regional or continental trade agreement, the AB must be legally permitted to participate in concomitant regional accreditation organizations or committees to represent the interests of its country. These regional organizations or committees are usually established to support ABs of the countries of the region in achieving international recognized accreditation, foster the use of accreditation activities within the region defined by the trade agreement and ensure accreditation in properly used in regional regulations and regional conformity assessment recognition agreements, and they are not the same as the regional cooperation bodies or groups. Examples of these types of arrangements can be found in Africa's continental quality policy and the Andean Community of Nations' Andean Accreditation Network.[108]

[108] African Union (2019), Africa Quality Policy, Final version adopted by STC-TIM on 3 September 2021, Pp 24-25 and ANDEAN COMMUNITY OF NATIONS. Available at: https://www.comunidadandina.org/notas-de-prensa/entra-en-funcionamiento-la-red-andina-de-acreditacion/



ANNEX 4:

SPECIFIC LEGAL CONSIDERATIONS: CONFORMITY ASSESSMENT AND CALIBRATION SERVICES

The local/regional set up of quality services should consider the following best practices:

1.

LEGAL STANDING OF CONFORMITY ASSESSMENT AND CALIBRATION SERVICES

A comprehensive strategy for the implementation of Conformity Assessment (CA) and calibration services, encompassing various aspects such as calibration laboratories and conformity assessment bodies offering testing, certification, inspection, verification, and validation services, among others, must be established to align with the country's quality policy. Local or regional legislation must contain the government's responsibilities regarding a national product certification scheme, the liberalization of product certification services regarding CA services, regulatory measures (i.e., private sector product certification given access in regulatory measures), and the role of accreditation in demonstrating technical competency of CAB.

CABs may be public or private bodies. It is essential that test laboratories, inspection, and product and management systems certification bodies possess a solid legal standing to provide CA services.

In principle and, regardless of its nature, the CAB should render its services using internationally recognized accreditation requirements. Accreditation schemes should not be divided into public and private schemes. In the event, the national regulator or policymaker needs the CAB to fulfill additional requirements in addition to those of accreditation to satisfy public policy or regulation; these requirements should be imposed on the CABs by the authority (separately from accreditation requirements and in addition to them) for the CABs to enter a process of administrative authorization. CABs providing CA services in the context of a regional common market could be subject to a recognition process by the relevant authorities in the regional market, which is the case for notified CABs in the EU. In addition, in some cases, the CAB needs to be recognized by the export market authorities.

To achieve this objective, the government must be legally allowed to build capacity in product certification and testing to meet the need of the markets in the most innovative, effective, and efficient ways. It is also important for the national product certification scheme to be formally recognized within the region through a multilateral recognition agreement (MRA), a multilateral arrangement (MLA) or other regional legislation mechanism.

Furthermore, on the economic development side, applicable legislation must determine how MSMEs should be supported through government programs to obtain CA services to upgrade the quality of their systems, products, and services.

Lastly, the legal aspect of conformity assessment extends to the recognition of accredited CA and calibration results as legally admissible evidence. Certification, validation, verification, inspection, testing and calibration results, among other things, may carry legal validity and can be presented as evidence before a court of law or before administrative authorities. Some QI primary legislation provides rules regarding the weight of such evidence, whether it is considered as prima facie evidence or subject to judicial notice of these results. In other cases, the judge may take judicial notice of the applicable technical standards to determine the state of the art of a product.

2.

LEGAL ENTITY OF CONFORMITY ASSESSMENT BODIES AND CALIBRATION LABORATORIES

Similarly, to other institutions, public CABs normally have their own legal entity and need to be established by primary legislation. In contrast, a private CAB and calibration laboratories can take various forms, such as commercial companies or not-for-profit organizations. In some jurisdictions, private CABs have the possibility to fulfill some administrative functions. It is important to note that, in such cases, the CAB will generally need to comply and behave as if it were a public entity. The applicable rules for the CAB will depend on its legal nature, roles and functions and the applicable administrative law of the country.

Overall, CABs and calibration laboratories need to be set up to comply with applicable ISO CASCO technical standards and other documents of a similar nature.

3.

PROTECTION AND SUPPORT TO ACCREDITED SERVICES

Different legal systems have different sanctions for fraud; however, as indicated above, it is recommended to prescribe in primary law that falsely claiming accreditation for services provided by a CAB or calibration laboratory is a punishable offence, akin to fraud, especially when the entity has not sought and maintained the AB's accreditation. This provision must go hand-in-hand with strict measures against the misuse of the accreditation mark.

Primary or secondary law must differentiate between accredited and non-accredited compulsory assessment services. It must give priority to the former over the latter when using them in regulatory settings or to achieve other policy or legal objectives, where such services are needed. In addition, primary or secondary law must indicate that government programs providing financial incentives for conformity assessment activities (under ISO CASCO rules) should give preference to accredited services over non-accredited alternatives.

4.

CABS AND CALIBRATION LABORATORY ACCREDITATION PROCESS

CABs and calibration laboratories should align their roles and functions with the requirements outlined in the ISO/IEC 17000 series that are relevant to their specific operations. Compliance with these technical standards is essential not only for obtaining accreditation but also for securing international recognition of CA and calibration results by other ABs via IAF/ILAC MLAs, which is a major benefit to CA services.

5.

DESIGNATED CABS

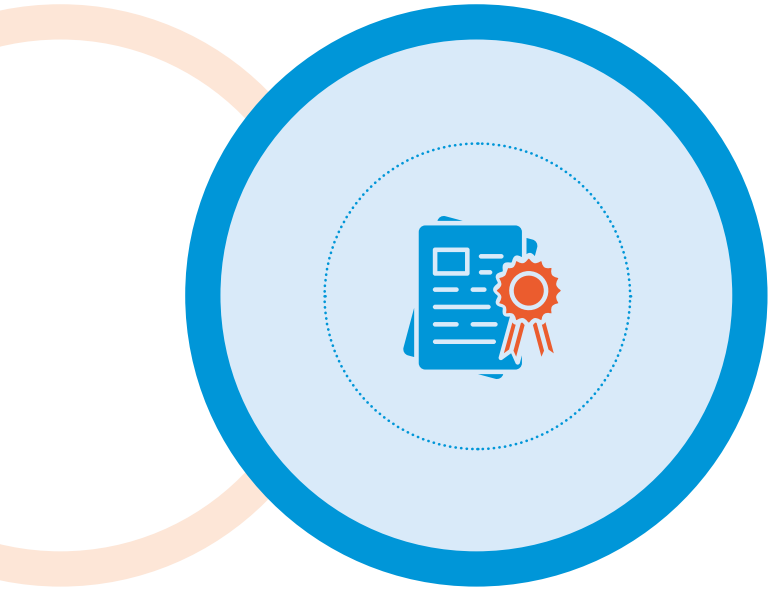
When test laboratories and product certification bodies in both the public and private sectors are selected to provide testing, inspection, and certification services for regulatory purposes, they need to be legally designated by the relevant authorities.

The designation of CABs must be allowed in legislation and must be based on the CABs' technical competence through accreditation to ISO/IEC 17020 for inspection, ISO/IEC 17025 for testing, ISO/IEC 17065 for product certification, ISO/IEC 17024 for personnel, ISO 15189 for medical laboratories and ISO/IEC 17029 for validation and verification, as needed. The applicable legislation must establish the legal responsibilities of these designated CABs within the country and define the applicable penalties for any offences committed.

6.

REGISTRATION OF TRAINED AUDITORS

It is recommended that auditors and lead auditors for system and product certifications audits must be appropriately trained, gain relevant experience, and be registered or listed as such. The establishment and maintenance of such a registration system may need to be organized by the government. In this case, legislation should explicitly grant the legal authority for the government to establish and manage this auditor registration system.



ANNEX 5:

SPECIFIC LEGAL CONSIDERATIONS ON THE REGULATORY ASPECTS OF LEGAL METROLOGY

For structured and detailed information on the Law on Metrology and its relationship to the legal QI framework, please refer to OIML's Guide (D-1)[109],BIPM-OIML publications on national metrology systems *Developing the institutional and legislative framework*, 2021[110],the International Vocabulary of Terms in Metrology (VIM)[111] and the International Vocabulary of Terms in Legal Metrology (VIML).[112] The following texts are some of the most salient sections of OIML's Guide (D-1). However, when drafting a metrology act, it is recommended to use these texts.

"Legal Metrology" is taken to comprise all the activities for which legal requirements are prescribed on measurement. It thus includes prescribed units of measurement, requirements on the use of measuring instruments or systems and methods of measurement, and activities performed by or on behalf of governmental authorities, in order to ensure an appropriate level of confidence in measurement results in the national regulatory environment. Legal metrology makes use of all developments in metrology to obtain appropriate references, metrological traceability and treatment of measurement uncertainty ('decision rules'). It may apply to any quantity addressed by metrology.

This aspect of legal metrology applies not only to trading parties, but also to the protection of individuals and society as a whole (e.g. law enforcement, health and safety measurements). Public authorities must pay special attention to measurement results and will need to rely on these results, especially when there are conflicting interests in measurement results, thus necessitating the intervention of an impartial referee.

Legal metrology is particularly necessary when there is imbalance between buyers and sellers in terms of knowledge or resources. Legal metrology generally includes provisions related to units of measurement, to measurement results (e.g. prepackages) and to measuring instruments and systems. These provisions cover the legal obligations related to the measurement results and the measuring instruments, as well as the legal control which is performed by or on behalf of the government.

Buying and selling of goods and services include the weighing or measuring of the quantity and/or quality of products, as well as prepackaged products with a weight, number or volume declaration of quantity, and the measurement of service (e.g. time, distance). Governmental regulatory responsibilities also include health, safety and environmental law. While these functions are disparate in nature, a common feature is that compliance with the law depends upon measurement results. Therefore, the process of measurement is of direct concern to the government. Providing the laws and regulations, controlling measurement through market supervision and developing and maintaining the infrastructure that can support the accuracy of these measurements (e.g. through traceability) is essential in fulfilling the role of government.

The scope of the legal metrology regulations (e.g. which types of measurements and measuring instruments or systems are subject to legal requirements) will depend on those markets that are important to the economy, on the categories of users that the government considers necessary to protect, and on the ability of these users to protect themselves against abuse.

Another key purpose of legal metrology is to provide confidence in measurement results by legal provisions. Needs and requirements on measurement results should be considered prior to addressing needs and requirements on measuring instruments.

***Legal metrology Regulations on measurements**, on*

[109] OIML (2020) D-1: 2020 (en) National metrology systems – Developing the institutional and legislative framework. Available at: https://www.oiml.org/en/files/pdf_d/d001-e20.pdf

[110] Idem

[111] OIML (2007) OIML V 2-200 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), Edition 2007 (E/F) Available at: https://www.bipm.org/documents/20126/54295284/VIM4_CD_210111c.pdf

[112] OIML (2022) International Vocabulary of Legal Metrology (VIML) – Digital Edition 2022 Available at: http://viml.oiml.info/en/index.html

prepackages and on measuring instruments are required in order to

- protect the interests of individuals and enterprises,
- protect national interests,
- protect public health and safety, including in relation to the environment and medical services, and
- ensure fair trade and level playing fields to promote trade.

These regulations ought, when applicable, to be compatible with OIML Recommendations and make use of their requirements. Other relevant OIML publications should also be considered.

The conformity assessment procedures required by these regulations should, when applicable, be compatible with the conformity assessment systems set up by the OIML, and, if appropriate, make use of them.

1.

REGULATIONS ON MEASUREMENTS

Depending on the areas it is wished to control, regulations may be required to

- *define measurement units to be used in legal transactions for various methods of sale,*
- *prescribe that certain measurements are to be used as the basis for transactions or law enforcement activities, and define the list of measurements subject to legal metrological requirements for the purposes listed in OIML D-1.*

These regulations need to define the metrological requirements (ordinarily including the required measurement uncertainty) and the legal control and supervision provisions applicable to these measurements in order to ensure confidence in the measurement results.

The results of measurements covered by the regulations mentioned in this section should be expressed in legal units and should be traceable.

These regulations may specify, when necessary, a measurement method, and may require the use of instruments subject to legal control. When necessary, they should specify the criteria for the choice of instruments such as accuracy class, measurement range, scale division, etc.

When necessary and for specific applications, these regulations may

- *define requirements applicable to the individuals or bodies who perform the measurements,*
- *require records of the measurement operations to be available to legal metrology officials,*
- *require the issuing of certificates for the result of these measurements.*

2.

REGULATIONS ON PREPACKAGES

Regulations may be made to set up metrological requirements and legal control provisions applicable to the quantity of product in prepackages offered or presented for sale or sold. In accordance with the OIML Convention and with the WTO/TBT Agreement, these regulations should be based on OIML Recommendations as far as possible.

These regulations should prescribe that the nominal quantity of product in prepackages be labelled on them and expressed in legal units. They may prescribe the authorised values of the nominal quantity of product in prepackages (standard pack sizes), and/or they may require that unit pricing information be provided at the point of sale.

These regulations should specify the tolerable deficiency of individual prepackages from their nominal value, and requirements for the conformity assessment of prepackages including statistical methods when necessary.

These regulations should specify the requirements to which the quantity of product in prepackages is subjected to determine acceptance or rejection, including sampling plans, test procedures and statistical methods and other appropriate guidance for legal metrology officials and pre-packers.

The regulatory requirements should take into account the equipment used for realising and controlling the prepackages, such as measuring container bottles, checkweighers, etc.

These regulations may define the marks which indicate the conformity (compliance) of the prepackages to the regulatory requirements.

These regulations may require manufacturers and importers of prepackages to be registered by the authorities. They may require importers to notify the authorities of importation(s) to facilitate inspections.

These regulations may prescribe that records of the control operations performed by the manufacturer or importer should be available to the legal metrology officials. They may prescribe that a quality system

be applied by the manufacturer or importer of the prepackages when appropriate.

These regulations may define the procedures and criteria for the legal control exerted by legal metrology officials on prepackages and on the sellers, packers, manufacturers and importers of prepackages.

All measurement results involving measuring instruments and measurement standards used for the controls prescribed in application of these regulations should be traceable to the SI.

These regulations may allow enforcement authorities to recognise the conformity to the national provisions of prepackages which bear marks of conformity affixed under the legal metrology regulations of other countries or under conformity marking systems set up by international bodies.

3.

REGULATIONS ON MEASURING INSTRUMENTS AND THEIR USE

Regulations should be made to define the list of measuring instrument categories subject to legal control.

The instruments subject to these regulations should provide measurement results in the legal units, and the measurement results should be traceable.

These regulations should specify the required metrological performance and technical requirements applicable to instruments in these categories.

In accordance with the OIML Convention and, when applicable, the WTO/TBT Agreement, these regulations should be based on OIML Recommendations as far as possible.

These regulations should set up legal control, including supervision, of these instruments. The purpose of this legal control is to ensure that instruments are fit for their intended use, meet and maintain the necessary metrological performance requirements and provide adequate protection against misuse, incorrect interpretations of results and fraud. The regulations should include the appropriate control and supervision procedures

- to assess the initial conformity of instruments to legal requirements, at the stage of design (e.g. type evaluation),
- to assess, at the stage of manufacturing, the conformity of instruments to type (when applicable) and their conformity to other legal requirements (e.g. initial verification),
- to ensure that instruments in service maintain their required metrological properties under expected conditions of use and with age (e.g. subsequent verification, in service inspection and field surveillance), or are withdrawn from use if they do not meet the requirements, and
- to ensure that instruments are correctly installed, used and operated under the defined correct conditions (e.g. environnemental).

These regulations should specify the markings and inscriptions which certify the status of the conformity of the instruments with legal requirements (e.g. type approval or verification marking).

A measuring instrument that no longer conforms to the legal requirements should be marked as rejected (and/or should have its verification marks removed) and should either be repaired or withdrawn from use.

In the event of infringements, equipment may be seized pending a decision of the legal authorities, or its further use may be prevented by appropriate means.

To prevent unauthorised adjustments or interventions, the regulations may restrict access to certain parts or functions of the instruments (including software). This access may be required to be physically protected by sealing (or protection of access to the software) defined by the regulations. Alternatively, or in addition, the regulations may require that the instruments adequately detect and record any access to these parts or functions.

These regulations may allow conformity assessment bodies to recognise instruments which conform with equivalent regulations in other countries. The regulations may allow conformity assessment bodies to enter into mutual acceptance or recognition arrangements and agreements with other countries, including the OIML Certification System (OIML-CS).

These regulations may allow the acceptance and utilisation in legal metrology controls of test or verification results issued in other countries.

The regulations may impose registration and other requirements for service agencies that install, adjust and maintain measuring instruments. The regulations should not conflict with other regulatory requirements applied to the agencies.

These regulations may set verification periods within which measuring instruments must be re-verified.

When measuring instruments are offered for sale, sold, or placed on the market for use subject to legal metrology requirements, the seller must inform the

buyer about the legal requirements/status, and offer instruments suitable for the intended use.

No person should use, possess for use or put into service for regulated applications, any measuring instrument subject to legal metrological control unless the instrument bears the required control marks, sealing marks or audit certificates.

The owner of or the person/organisation responsible for a measuring instrument subject to legal metrology regulations is required to maintain the conformity of that instrument to legal requirements (including controls on accuracy) while it is in service. Use of the instrument should also comply with all operating instructions and maintenance requirements supplied by the manufacturer.

4.

CONFORMITY ASSESSMENT FRAMEWORK

The enforcement of the regulations generally requires the use of appropriate conformity assessment procedures. Conformity assessment procedures may be required

- at the stage of the design of a type of instrument (see definition of a type),
- at the stage of the production of instruments or prepackages, before placing them on the market,
- at the stage of installing and putting an instrument into service,
- at the stage of repair of an instrument, before putting it back into service, and
- during the lifetime of the instrument in use.

Applicable conformity assessment procedures should be defined by an appropriate legal document, in application of the Law on Metrology.

It is recommended that these conformity assessment procedures be defined according to the guidance given in the relevant OIML publications.

When the OIML Certification System (OIML-CS) covers a given category of measuring instrument, it is recommended that the national conformity assessment procedures for those instruments take the OIML- CS into account.

When conformity assessment procedures in another country comply with OIML Recommendations and Documents, the national conformity assessment procedures should take this into consideration.

Either the central government authority or the legal metrology authorities should decide whether an OIML-CS certificate or a foreign conformity assessment result is recognised to be as equivalent to the national conformity assessment. These authorities should also be in charge of the corresponding national conformity assessment procedures.

OIML Recommendations generally present recommended conformity assessment procedures applicable for Member States.

5.

SURVEILLANCE FRAMEWORK

In addition to the legal metrology procedures and to the supervision and coordination of the activities carried out by the bodies appointed for specific legal metrology tasks, a general surveillance must be exerted by the enforcement authorities. Enforcement is an essential component of legal metrology and must be carried out by or on behalf of the state.

The surveillance is composed of

- *surveillance of bodies or persons to which obligations are made by the regulations,*
- *market surveillance,*
- *surveillance of the use of instruments, and*
- *surveillance of the correct use of units of measurement.*

The purpose of the surveillance of bodies or persons involved in legal metrology activities is to detect non compliances of these persons or bodies with their obligations, for example:

- *obligation to put on the market only instruments complying with the regulation when applicable;*
- *obligation to give notice of installation or repair of measuring instruments when this is required;*
- *obligation to affix legal marks on instruments and prohibit the removal of required marks;*
- *obligation to use measuring instruments according to the regulatory conditions when required;*
- *prohibition on tampering with instruments;*
- *obligation to submit instruments to regulatory verification when required; and*
- *obligation to have instruments maintained when required.*

All the persons subject to regulations under the Law on Metrology have the obligation to

allow enforcement authorities to carry out their surveillance tasks and to provide them with relevant information upon request.

A mix of appropriate market surveillance activities, carried out by enforcement authorities, can provide market confidence to those adopting good metrology practice.

Manufacturers and prepackers gain assurance from surveillance activities carried out by enforcement authorities testing the robustness of systems and providing informed, impartial, technical feedback.

6.

LEGAL FRAMEWORK – OTHER PROVISIONS

It is necessary that the offences that arise from non-compliance with the obligations of the Law on Metrology are clearly listed, with corresponding penalties, in an appropriate law.

These penalties should be proportionate to the offences and consistent across the various areas of regulation as far as possible. This consistency is most easily achieved if they are contained in a general Law on Metrology.

In specifying offences it is necessary to consider a number of different offences:

» *General offences, such as*

- selling, offering, or exposing for sale a quantity less than the quantity represented, as prescribed in regulations (which may account for statistical variation),
- taking, as a buyer, more than the represented quantity,
- misrepresenting the quantity in any manner to mislead or deceive another person,
- misrepresenting the price of any commodity or service sold, offered, exposed, or advertised for sale by quantity (weight, measure, or count/number), or misrepresenting the price in any manner to mislead or deceive a person,
- misrepresenting measurements of quality of products used to determine the price or grade of the product,
- failing to register when registration is required,
- not complying with obligations to keep records, or not making them available to legal metrology officials,
- not complying with corrective actions requested/instructed by legal metrology officials,
- hindering or obstructing any legal metrology official in the performance of their duties,
- affixing fake or undue conformity marking or verification marks, and
- impersonating a legal metrology official;

» *Offences related to measurements provided in advertisements or other public communications;*

» *Offences related to the use of legal units;*

» *Offences related to regulations on measurements;*

» *Offences related to regulations on prepackages;*

» *Offences related to measuring instruments for which legal control is required.*

It is also desirable to have a clear statement of the responsibilities of those who use, keep, import, manufacture, repair, sell or rent measuring instruments or equipment intended for uses covered by the national legislation on metrology.

In addition, it is necessary to make provisions for enforcement powers.

Considerations to be addressed when drawing up provisions on enforcement powers, offences and penalties and the responsibilities.

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

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