Systemic Approaches to Quality Infrastructure

A comparative study between Germany and Mexico

GPQI
Dialogues for Innovation and Trade

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Global Project Quality Infrastructure (GPQI)

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Standardisation and Conformity Assessment Body

SIAAC Sociedad Internacional de Acreditación A.C. (SIAAC)
SIAAC International Accreditation Society

About this publication

Quality infrastructure – A concept for trust and security in world trade and development

Quality infrastructure (QI), as a comprehensive system, ensures that the products and services we use in our everyday life are fit for purpose, safe to use and comply with environmental standards. The individuals and organisations involved in QI participate in a range of activities, such as developing product and process standards, conducting conformity assessment, the accreditation of conformity-assessment bodies, and overseeing national metrology and market surveillance. These activities are interconnected and interact in a systemic way.

Germany supports the international harmonisation of QI

The German Federal Ministry for Economic Affairs and Climate Action (Bundesministerium für Wirtschaft und Klimaschutz, BMWK) established the Global Project Quality Infrastructure (GPQI) in 2017. GPQI aims to reduce barriers to trade and increase consumer protection worldwide through the international harmonisation of QI. It has so far been implemented in Brazil, China, India, Indonesia and Mexico with the support of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH. As part of the project, experts from national QI institutions and the private sector work together in political and technical dialogues, aiming to generate a better mutual understanding of national QIs and promote convergence in QI systems.

German-Mexican Dialogue on Quality Infrastructure

The German-Mexican Dialogue on Quality Infrastructure was established in 2018 between BMWK and the Mexican Ministry of Economy (Secretaría de Economía). It is a platform for political and technical dialogue that seeks to address the concerns and interests of the different stakeholders within both QI systems. Government entities, the private sector and the QI institutions of both countries are actively involved. Since 2018, activities related to various pillars of QI have been promoted, encompassing areas such as machinery safety, electromobility, and cybersecurity, among others.

A Publication on Quality Infrastructure in Mexico and Germany

This comparative study is a product of the German-Mexican Dialogue on Quality Infrastructure. It aims to enhance understanding of the similarities and differences between quality infrastructure systems in Mexico and Germany, and how the various elements of QI contribute to achieving high-quality, compliant products and services. The study is particularly targeted at officials, policymakers and experts in both countries who trade or wish to deepen economic ties. We also invite experts from industry associations and companies, research and academia, and anyone else interested in reading this publication.

A joint effort by Mexican and German QI stakeholders and institutions

The starting point for this study was the cycle of workshops "A Systemic Approach to Quality Infrastructure Mexico – Germany" held between March and November 2021 and the study "United in Quality and Safety" published by BMWK. Information collected from interviews with representatives of the Mexican QI System enriched the contents of this document.

Contents

List of abbreviations

AAMÜ	**Arbeitsausschuss Marktüberwachung** *Working Committee on Market Surveillance (Germany)*
AkkStelleG	**Gesetz über die Akkreditierungsstelle (Akkreditierungsstellengesetz)** *Accreditation Body Act (Germany)*
ANFAD	**Asociación Nacional de Fabricantes de Aparatos Domésticos** *National Association of Household Appliance Manufacturers (Mexico)*
ANCE	**Asociación de Normalización y Certificación A.C.** *Association for Standardisation and Certification (Mexico)*
ANSI	**American National Standards Institute** *(private, non-profit organisation that administers and coordinates the U.S. voluntary standards and conformity assessment system)*
APAC	**Asia Pacific Accreditation Cooperation Incorporated**
ASTM	**American Society for Testing and Materials**
BAM	**Bundesanstalt für Materialforschung und -prüfung** *Federal Institute for Materials Research and Testing*
BAuA	**Bundesanstalt für Arbeitsschutz und Arbeitsmedizin** *Federal Institute for Occupational Health and Safety (Germany)*
BDI	**Bundesverband der Deutschen Industrie** *Federation of German Industries (Germany)*
BIPM	**Bureau International des Poids et Mesures** *International Bureau of Weights and Measures*
BMG	**Bundesministerium der Gesundheit** *Federal Ministry of Health (Germany)*
BMU	**Bundesministerium für Umwelt, Naturschutz und nukleare Sicherheit** *Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Germany)*
BMVI	**Bundesministerium für Verkehr und Digitale Infrastruktur** *Federal Ministry of Transport and Digital Infrastructure (Germany)*
BMWK	**Bundesministerium für Wirtschaft und Klimaschutz** *Federal Ministry for Economic Affairs and Climate Action (Germany)*
BMZ	**Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung** *Federal Ministry of Economic Cooperation and Development (Germany)*
BNetzA	**Bundesnetzagentur** *Federal Network Agency for Electricity, Gas, Telecommunications Post and Railway (Germany)*

BVL	**Bundesamt für Verbraucherschutz und Lebensmittelsicherheit** *Federal Office of Consumer Protection and Food Safety (Germany)*
CA	**Conformity Assessment**
CABs	**Conformity Assessment Bodies**
CANACERO	**Cámara Nacional de la Industria del Hierro y del Acero** *National Chamber of the Iron and Steel Industry (Mexico)*
CCN-NAN	**Comités Consultivos Nacionales de Normalización de las Autoridades Normalizadoras** *National Standardisation Advisory Committees of the Standardisation Authorities (Mexico)*
CE	**Communauté/ Conformité Européenne** *European Community/ Conformity*
CEN	**European Committee for Standardization**
CENAM	**Centro Nacional de Metrología** *National Metrology Centre*
CENELEC	**European Committee for Electrotechnical Standardization**
CETA	**EU-Canada Comprehensive Economic and Trade Agreement**
CMC	**Calibration and Measurement Capabilities**
CNCP	**Centro de Normalización y Certificación de Productos** *Centre for the Standardisation and Certification of Products (Mexico)*
CNIC	**Comisión Nacional de Infraestructura de la Calidad** *National Commission on Quality Infrastructure (Mexico)*
COFOCALEC	**Consejo para el Fomento de la Calidad de la Leche y sus derivados** *Council for the Promotion of the Quality of Milk and Dairy Products (Mexico)*
COMENOR	**Consejo Mexicano de Normalización y Evaluación de la Conformidad, A. C.** *Mexican Council for Standardisation and Conformity Assessment*
CONCAMIN	**Confederación de Cámaras Industriales de los Estados Unidos Mexicanos** *Confederation of Industrial Chambers of Mexico*
CONACYT	**Consejo Nacional de Ciencia y Tecnología** *National Council of Science and Technology (Mexico)*
COPANT	**Comisión Panamericana de Normas Técnicas** *Pan American Standards Commission*
DAkkS	**Deutsche Akkreditierungsstelle** *Germany's national accreditation body*
DEKRA	**Deutscher Kraftfahrzeug-Überwachungs-Verein** *German Motor Vehicle Inspection Association*
DGLNPC	**Dirección General de Laboratorio Nacional de Protección al Consumidor** *Directorate General of the National Consumer Protection Laboratory (Mexico)*
DGN	**Dirección General de Normas** *General Bureau of Technical Regulations and Standards (Mexico)*

DI	**Designated (Metrology) Institutes**
DIN	**Deutsches Institut für Normung** *Association of German Institute for Standardisation*
DKD	**Deutscher Kalibrierdienst** *German Calibration Service*
DKE	**Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE** *German Commission for Electrical, Electronic & Information Technologies of DIN and VD*
DMÜF	**Deutsches Marktüberwachungsforum** *German Market Surveillance Forum*
DOF	**Diario Oficial de la Federación** *Official Gazette of the Federation (Mexico)*
DNP	**Deutscher Normalisierungspanel** *German Standardisation Panel*
EA	**European co-operation for Accreditation**
ema	**entidad mexicana de acreditación A.C.** *Mexican Accreditation Body*
EU	**European Union**
EURAMET	**European Association of National Metrology Institutes**
EVPG	**Energieverbrauchsrelevante-Produkte-Gesetz** *Energy Consumption-Related Products Act (Germany)*
FTA	**Free trade agreement**
GDP	**Gross domestic product**
GIZ	**Deutsche Gesellschaft für Internationale Zusammenarbeit**
GPQI	**Global Project Quality Infrastructure**
GPSD	**General Product Safety Directive**
GRP	**Good Regulatory Practice**
GS	**Geprüfte Sicherheit** *"Tested Safety" (mark)*
IAAC	**Inter-American Accreditation Cooperation**
IAF	**International Accreditation Forum**
ICSMS	**Information and Communication System on Market Surveillance (EU)**
IEA	**International Energy Agency**
IEC	**International Electrotechnical Commission**
IECEE CB	**IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components Certification Body**

IFC	**Instituto para el Fomento a la Calidad Total, A.C.** *Institute for Total Quality Promotion (Mexico)*
ILAC	**International Laboratory Accreditation Cooperation**
IMEEC	**Instituto Mexicano de Normalización y Certificación A.C. ahora IMEEC** *Mexican Institute for Standardisation and Certification A.C., now IMEEC*
INECC	**Instituto Nacional de Ecología y Cambio Climático** *National Institute of Ecology and Climate Change* *(Designated Metrology Institute for ozone concentration) (Mexico)*
INetQI	**International Network on Quality Infrastructure**
ININ	**Instituto Nacional de Investigaciones Nucleares** *National Institute for Nuclear Research* *(Designated Metrology Institute for ionizing radiation) (Mexico)*
INNTEX	**Instituto Nacional de Normalización Textil** *National Institute for Textile Standardisation (Mexico)*
ISO	**International Organization for Standardization**
ITU	**International Telecommunication Union**
KBA	**Kraftfahrt-Bundesamt** *Federal Motor Transport Authority (Germany)*
LFMN	**Ley Federal sobre Metrología y Normalización** *Federal Law on Metrology and Standardisation (until 2020)*
LIC	**Ley de Infraestructura de la Calidad** *Quality Infrastructure Law*
MAAC	**Mexicana de Acreditación A.C.**
MessEG	**Mess- und Eichgesetz** *Measures and Verification Act (Germany)*
MLA	**Multilateral recognition agreement/multilateral agreement**
MRA	**Mutual recognition agreement/arrangement**
NAFTA	**North American Free Trade Agreement (NAFTA)** **(before June 30, 2020)**
NAM	**DIN-Normenausschuss Maschinenbau** *DIN Standards Committee Mechanical Engineering (Germany)*
NANDO	**New Approach Notified and Designated Organisations (EU)**
NIST	**National Institute of Standards and Technology (USA)** *(National Metrology Institute of the USA)*
NLF	**New legislative framework (European Union)**
NMI	**National Metrology Institute**
NMX	**Normas Mexicanas** *Mexican Standards*

NOM	**Normas Oficiales Mexicanas** *Mexican Technical Regulations*
NORMEX	**Sociedad Mexicana de Normalización** *Mexican Society for Standardisation (Mexico)*
NSB	**National Standardisation Body**
NYCE	**Normalización y Certificación NYCE, SC** *Standardisation and Certification Body (Mexico)*
OIML	**Organisation Internationale de Métrologie Légale** *International Organisation of Legal Metrology*
OIML-CS	**OIML certification system**
OJEU	**Official Journal of the European Union**
ONN/ NSB	**Organismo Nacional de Normalización** *National Standardisation Body*
ONNCCE	**Organismo Nacional de Normalización y Certificación de la Construcción y Edificación** *National Organisation for Standardisation and Certification in Construction (Mexico)*
ONNPROLAC	**Organismo Nacional de Normalización de Productos Lácteos, A.C.** *National Standardisation Body for Dairy Products (Mexico)*
PLATIICA	**Plataforma Tecnológica Integral de Infraestructura de la Calidad** *Integral Technology Platform for Quality Infrastructure (Mexico)*
PNC	**Premio Nacional de Calidad** *National Quality Award*
ProdSG	**Produktsicherheitsgesetz** *German Product Safety Act*
PROFECO	**Procuraduría Federal del Consumidor** *Federal Consumer Protection Agency (Mexico)*
PTB	**Physikalisch-Technische Bundesanstalt** *National Metrology Institute of Germany*
RAL	**Deutsches Institut für Gütesicherung und Kennzeichnung e. V.** *German Institute for Quality Assurance and Labelling*
QI	**Quality infrastructure**
QICA	**Quality Infrastructure Council of the Americas**
RAPEX	**EU rapid alert system for dangerous non-food products** *(Rapid Exchange of Information System)*
SE	**Secretaría de Economía** *Mexican Minstry of Economy*
SECOFI	**Secretaría de Comercio y Fomento Industrial** *(Former) Ministry of Commerce and Industrial Development (Mexico)*

SENASICA	**Servicio Nacional de Sanidad, Inocuidad y Calidad** *National Health, Safety and Quality Service*
SAT	**Servicio de Administración Tributaria** *Tax Administration Service (Mexico)*
SI	**Système international d'unités** **International System of Units**
SIAAC	**SIAAC Sociedad International de Acreditación, A.C.** *SIAAC International Accreditation Society*
SIM	**Sistema Interamericano de Metrología** *Inter-American Metrology System*
SNIC	**Sistema Nacional de Infraestructura de la Calidad** *National Quality Infrastructure System (Mexico)*
TBT	**Technical Barriers to Trade**
TEU	**Treaty on European Union**
TFEU	**Treaty on the Functioning of the European Union**
TransMeT	**Transfer von messtechnischen Technologien** *Transfer of Metrological Technologies*
TRIS	*Technical Regulations Information System database (EU)*
TÜV	**Technischer Überwachungsverein** *Technical inspection association (Germany)*
UBA	**Umweltbundesamt** *German Environment Agency*
UNIDO	**United Nations Industrial Development Organization**
UNECE	**United Nations Economic Commission for Europe**
USA	**United States of America**
USMCA	**U.S. – Mexico – Canada Agreement**
VDE	**Verband der Elektrotechnik Elektronik Informationstechnik** *Association for Electrical, Electronic & Information Technologies (Germany)*
VDMA	**Verband Deutscher Maschinen- und Anlagenbau German Mechanical Engineering Industry Association (Germany)**
WELMEC	**European Cooperation in Legal Metrology** *(earlier: Western European Legal Metrology Cooperation)*
WTO	**World Trade Organization**
ZLG	**Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten** *Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (Germany)*
ZLS	**Zentralstelle der Länder für Sicherheitstechnik** *Central Authority of the Federal States for Safety Engineering (Germany)*

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Executive summary

Why compare the Mexican and German QI systems?

As part of this endeavour, it is vital to understand the similarities and differences between the QI systems of different countries. In the case of Mexico and Germany, this is particularly important given their strong trade partnership: The volume of trade between the two countries ascended to about 20 billion euros in 2022, while around 2,000 firms with German capital are based in Mexico. To strengthen this relationship further, it is necessary to deepen the mutual understanding of the two national QI systems and to collaborate on reducing remaining technical barriers to trade. Moreover, this publication aims to identify "inspiring practices" in QI in each case, opening up ways for mutual learning, new areas of collaboration, and ensuring that each country contributes towards the international harmonisation of QI with its own strengths and expertise.

The Mexican QI system

With the Quality Infrastructure Law (LIC) replacing the Federal Law on Metrology and Standardisation in 2020, Mexico's government has laid the foundation for a fundamental realignment of the QI system. The new legal framework follows a systemic approach to QI, specifying the division of labour and coordination between different QI institutions. The Ministry of Economy (Secretaría de Economía) is responsible for coordinating and overseeing all QI activities, while the National Commission for Quality Infrastructure, consisting of the subdivisions concerned with QI in each ministry, sectoral regulation bodies and business associations is responsible for annually reviewing, analysing and approving the National Quality Infrastructure Programme that contains all standardisation initiatives.

The German QI system

As Germany is a member state of the European Union and part of the European Single Market, the legal framework and the institutions dealing with QI are determined not only at the national level but are in line with EU level and international agreements, for example as part of the technical harmonisation of the European Single Market. Within Germany, the BMWK is the competent and supervisory authority for various German QI bodies, including the national metrology institute (PTB) and the German Institute for Standardisation (DIN). At the same time, the sixteen Federal States are responsible for market surveillance activities in their respective territories, with the BMWK assuming a coordinating and moderating function in the system.

Case study offering practical guidance

To facilitate the understanding of the practical functioning of QI in both countries, at the end of each chapter the relevant element of the QI system is explained with reference to the example of a refrigerator. In these sections, the importance of different QI elements for guaranteeing the safety and fitness-for-purpose of the refrigerator is highlighted, as well as the standards and regulations that apply in both countries.

Similarities and differences between the Mexican and German QI systems

Following the signing of the North American Free Trade Agreement (NAFTA) in 1994, Mexico bolstered its institutional framework for QI to facilitate its trade relations with treaty partners. The impact of this trade partnership contrasts with Germany's frame of reference and institutional setup. In both Germany and Mexico, the development of QI systems has spanned many years, even though the term "QI" itself is relatively recent. Notably, Mexico took the pioneering step of implementing comprehensive legislation covering all QI institutions.

Although both countries are federal states, Germany's market surveillance competencies are decentralised, whereas in Mexico, several

federal ministries are both responsible of issuing technical regulations and performing market surveillance activities with respect to their regulations. Moreover, a characteristic of the German standardisation system is its self-administration by industry chambers. In contrast, in Mexico the Ministry of Ecoomy with the General Bureau of Technical Regulations and Standards (Dirección General de Normas - DGN) has an important role coordinating the National Standardisation Bodies, which oversee the development and modification of standards. Regardless of their particularities, both QI systems are integrated into the international system of mutual recognition.

Inspiring Practices

The comparison between the evolution of different QI elements in Mexico and Germany allows for the identification of a set of "inspiring practices" in each case. Mexico stands out in the successful efforts to integrate Sustainable Development Goal (SDG) 5, gender equality, in QI institutions through the activities of the Association of Women in the System of Quality Infrastructure (MUSICA). Also, its systemic approach to QI based on the Quality Infrastructure Law promotes coherence and transparency in the QI system and facilitates coordination between different actors.

On the other hand, the German decentralised market surveillance system allows for an efficient surveillance of products circulating in the respective territories based on state-specific targeting. Furthermore, the separation between essential product requirements and voluntary technical standards as part of the EU New Legislative Framework allows for the development of fast responses to technological changes, reduces the burden on public authorities, and stimulates innovation.

Perspectives for the QI systems

QI systems in both countries are continuously evolving and adapting to new conditions and challenges. Key challenges include digitalisation and the transformation towards sustainable and climate-neutral economies as part of the Paris Agreement. In terms of digitalisation, these challenges include digitalising QI itself, as envisioned by the Mexican integral electronic platform PLATIICA, and supporting businesses in their respective digitalisation strategies with metrology, standards and conformity assessment (CA) services. German experts are actively working on making QI fit for the digital age. One initiative is the "QI Digital" consortium, jointly founded by BAM, DAkkS, DIN, DKE and PTB and supported by BMWK. Its goal is to develop a vision of QI for the digital age.

One important field of climate action is the transition from a linear to a circular economy. In this field, the Mexican QI institutions are participating in a regional project of GIZ with the Organization of American States (OAS) of the Quality Infrastructure Council of the Americas (QICA) on quality infrastructure for the circular economy (QI4CE), aiming to identify companies' QI needs in the developing circular economy.

The close collaboration between Mexico and Germany on QI and their importance as major trade partners in the automotive industry, mechanical engineering, chemicals, and other industries open up unique opportunities for collaboration in the face of these new challenges.

1. Introduction

QI serves a modern and internationalised economy whilst protecting people, health and the environment.

QI services work behind the scenes to enable consumers to trust that the products they buy are safe and sound. The interaction of metrology, standardisation, CA and market surveillance ensure that economic transactions between companies run smoothly. This applies to the national market as well as to international trade. In an increasingly complex globalised world, the role of QI as a broker of trust is becoming increasingly important. Furthermore, QI has an impact beyond trade, contributing to protecting the climate and the environment as well as the health and well-being of the population.

International trade and consumer protection requires QI.

Mexico and Germany are both strongly industrialised and trading nations. Both countries are founding members of the World Trade Organization (WTO) and benefit from open and rules-based world trade.

Germany is a member of the European Union (EU) and part of the European Single Market which consists of 450 million people, while Mexico forms part of the North American Free Trade Agreement (USMCA) comprising 600 million people. Both the EU and the North American Free Trade Area are among the world's major trading blocs, maintaining intensive trade relations and agreements with each other.

Due to the great importance of trade for the national economy, both countries invest in their QI. Their services enable national companies to meet target market safety and quality requirements. QI helps held companies to save costs and innovate with products, processes, and forms of organisation. The availability of QI services also attracts foreign direct investment. Moreover, quality infrastructure helps to protect consumers at the domestic level.

Systemic understanding of QI

The concept of a quality system has its origins in management. A quality management system (QMS) is a formalised system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and control an organisation's activities to meet customer and regulatory requirements and continuously improve its effectiveness and efficiency.

The concept of QI transfers ideas of the quality management system to a national economy. The system consists of four central components: Standards define the quality criteria and are based on best practices; CA verifies that products and services meet requirements; accreditation confirms the technical competence and independence of conformity assessment bodies (CABs), and finally metrology, which ensures the comparability of weights and measures and anchors the system scientifically[2].

These components interact regularly and are interdependent. For example, a company uses a certificate to prove that their product or service meets the quality and safety requirements. The body issuing this certificate may require a test. The laboratory that performs the test must calibrate its measuring instruments and prove its technical competence through accreditation. All QI service providers, in turn, refer to standards and regulations. Together, these players in different fields are part of a unified whole, the national quality infrastructure system.

QI articulates itself as a national system. In different countries, QI institutions emerged at different times, often in response to concrete challenges posed by the national economy. In this respect, QI must continuously adapt and develop. At the same time, the culture of the country and its Quality and safety without borders: The importance of international cooperation trading partners also shapes the national QI. For example, Mexico's QI developed in the context of the North American

[2] Mexico, just like most of the world's economies, is a member of the Metre Convention. The Committee International of Weights and Measures, CIPM, is committed within the Metre Convention to ensure the uniformity of measurements in the world. The CIPM postulated a Mutual Recognition Arrangement, CIPM MRA, in year 2000, where the National Institutes of Metrology are committed themselves to look after the comparability of weights and measures and anchors the system scientifically. In Mexico, the Centro Nacional de Metrología, CENAM, has been appointed as the National Metrology Institute at the CIPM MRA.

economic area, but also took inspiration from its European trading partners (especially Germany). QI in Mexico and Germany refers to a common international reference framework. This includes the agreements in the Technical Barriers to Trade (TBT) Agreement of the World Trade Organization (WTO), as well as the agreements of mutual recognition of QI services in the field of accreditation. This guarantees that the test for a product in one country is also recognised in the other country. This principle prevents double testing and reduces transaction costs for companies.

Quality and safety without borders: The importance of international cooperation

Although the systems in each country have their specific characteristics, QI is now globally integrated and supports international trade. It is based on internationally harmonised standards developed by economic actors in many countries in international standards organisations such as the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and International Telecommunication Union (ITU).

CABs assess the compliance with these standards. Their competence is guaranteed by accreditation bodies that mutually recognise each other's services via international agreements and enables a product that has been tested once to be accepted everywhere. The international metrology system guarantees that all measurements can be traced back to an international system of units of measurement (SI), and are thus comparable.

However, the concept of QI itself is relatively new in both countries. It describes the system for metrology, standardisation, testing and quality management that arose as a result of international development cooperation. At the beginning of the 2000s, the international cooperation of the German National Metrology Institute (PTB) and the United Nations Industrial Development Organization (UNIDO) were the first to coin the term QI. Mexico, in turn, is a pioneer in using the term QI to refer to the system-wide national Quality Infrastructure Law (LIC).

Germany's Global Project Quality Infrastructure (GPQI)

Germany has been collaborating with other countries for many years to promote the global standardisation of QI. In 2017, the BMWK created the Global Project Quality Infrastructure (GPQI) to strengthen this undertaking. The GPQI works with major trading partners like Brazil, China, Mexico, India, and Indonesia, and involves stakeholders from public and private sectors, standardisation and accreditation bodies, metrology institutes, and technical and scientific institutions. This project aims to reduce trade obstacles caused by technical differences and enhance product safety and consumer protection.

Overview of this publication

This publication aims to provide an easy-to-understand overview of QI in Mexico and Germany. The following two chapters describe QI, its legal basis, and its components, such as standardisation and technical regulations CA, accreditation, metrology and market surveillance in each of the two countries. This is followed by a chapter highlighting the similarities and explaining the differences. New trends, such as the contributions of QI to digitalisation and sustainable development, are also addressed.

As an illustrative example, a refrigerator is used to explain to the readers the practical importance of QI services in Mexico and Germany. The publication concludes with a series of literature references for those who wish to study QI in both countries in more detail.

The refrigerator: Product case toillustrate QI application

A refrigerator is a commercial and domestic appliance consisting of a thermally insulated compartment and a heat pump (mechanical, electronic or chemical) that transfers heat from the interior to the external environment so that the interior is cooled to a temperature below room temperature. Refrigerators enhance the hygienic storage of perishables, directly impacting human health through the preservation of nutrients and the reduction in illness (Craig, Goodwin, Grennes, 2004)[3].

Access to cooling technology also has a positive effect on household finances, as it reduces food waste and enables a more effective allocation of funds designated for food expenses (Rolfsman, Tiljander, 2020)[4]. With the development of refrigeration technology and mass production, the cost of refrigerators fell continuously. Today, every household in Germany has a refrigerator.[5] In Mexico, 88% of households has one.[6]

In addition to purchasing a refrigerator, energy costs are an important selection factor. In this respect, special emphasis is now placed on energy efficiency. Special labels inform consumers about household appliance energy efficiency and other performance criteria. This is part of consumer protection and responds to the need for information. The electrical operation of refrigerators also poses risks to the safety of the users. In this respect, safety standards must be observed in refrigerators' manufacture, maintenance, and operation. Corresponding safety regulations and tests meet the need for safety. In this area, the state also assumes a protective function that allows it to regulate markets accordingly. Even highervalue needs can be satisfied by buying a refrigerator. For example, the industry is producing freezers that make fresh ice cubes at the touch of a button or smart fridges that send us a push message on our smartphone if we have left the door open. Refrigerator technology is responding to new trends such as sustainability and digitalisation, and manufacturers are continuously developing it further. Refrigerators are a frequently traded commodity in both countries and must meet many requirements in terms of quality and safety.

In 2019, refrigerators[7] accounted for a total trade of $47 billion, representing 0.26% of total world trade. The leading exporting nations of refrigerators were China ($11.1 billion), Mexico ($5.16 billion), Italy ($3.27 billion), the United States ($2.6 billion) and Germany ($2.5 billion). The top importers of refrigerators were the United States ($9.05 billion), Germany ($3.25 billion), France ($2.32 billion), the United Kingdom ($1.84 billion) and Canada ($1.55 billion). Mexico exported $5.16 billion worth of refrigerators, making it the second-largest exporter of refrigerators in the world. In the same year, refrigerators were Mexico's 14th most exported product. Germany exported $2.5 billion of refrigerators, making it the fifth-largest exporter of refrigerators in the world. Currently, the refrigerators trade between Germany and Mexico is relatively small, amounting to $3-4 million per year.

[7] The Harmonised System assigns HS code 8418 to refrigerators and freezers that are electrically or non-electrically operated.

2. The Mexican QI System

2.1 Context and framework

Key points in this section:

- **Mexico is an open economy with high trade potential.**
- **The Quality Infrastructure Law renews the entire system of standardisation, technical regulation, CA, accreditation, metrology, and market surveillance.**
- **As of this document's issuance date in December 2023 the law has not yet been implemented in an ordinance. Therefore, Mexico's QI system is experiencing a transitional phase.**

Open economy

Mexico has one of the most open economies in the world. With ongoing industrialisation, favourable demographics, rising domestic consumption and proximity to the US market, Mexico's economy has considerable potential.

WTO Membership and Free Trade Agreements

The country has been a co-founder and member of the World Trade Organization (WTO) since 1 January 1995 and was one of the first signatories of the Agreement on Technical Barriers to Trade (TBT). The country has played an active role in implementing this international instrument and seeks to eliminate unnecessary TBT by applying uniform rules and procedures. Mexico participates in exchanging information on mutual recognition agreements (MRAs) on conformity services and continues to cooperate on regulatory issues with other WTO Members to facilitate trade.

Mexico has thirteen free trade agreements (FTAs) with 50 countries, including the United States-Mexico-Canada Agreement (USMCA), the European Union, the European Free Trade Association (EFTA), Japan, Israel, several countries in Latin America and the comprehensive and progressive Trans-Pacific Partnership agreement. Mexico is also a member of the Pacific Alliance, a trade bloc formed in 2011 by Mexico, Chile, Colombia and Peru.[8]

United States-Mexico-Canada Agreement

With the North American Free Trade Agreement (NAFTA), which came into force on 1 January 1994, Mexico became part of the common economic area with Canada and the United States of America. This agreement enabled Mexican manufacturers to position themselves as preferred suppliers to northern trading partners. The reduction of tariffs and non-tariff barriers stimulated exports and imports.

On 1 July 2020, USMCA entered into force, replacing NAFTA. The new agreement deepens the economic integration of the North American market. Products originating in the zone can be traded duty-free within the zone. Specific agreements improve the mutual recognition of regulatory requirements, especially in the pharmaceutical, medical devices, and chemical industries. The agreement also increases duty-free allowances

for courier shipments in cross-border trade between trading partners.[9]

In addition to eliminating tariffs, the parties to the agreement also agreed to remove TBT. USMCA stipulated that the contracting parties should make CA procedures for product standards as compatible as possible with the procedures of the other parties. CABs of the other parties should, as far as possible, recognise and accredit them as equivalent to their domestic institutions.

OECD Membership

NAFTA accession enabled Mexico's membership in the Organization for Economic Cooperation and Development (OECD) only four months later. Mexico became the 25th OECD member country and the first Latin American country to belong to the club of industrialised countries.

The OECD particularly supported Mexico in modernising its regulation process. The 2018 examination of the Technical Regulatory System confirmed that Mexico had shown a strong commitment to uphold high standards in its laws and technical regulations (Normas Oficiales Mexicanas - NOMs). Mexico's efforts have focused on the early stages of the "regulatory life cycle", which mainly focuses on the design of laws and regulations. However, adequate enforcement is needed to achieve the desired outcomes of technical regulations.[10]

The Mexican government aims to overcome these shortcomings with the new Quality Infrastructure Law and promote a "culture of compliance".

EU-Mexico Global Agreement

In the early 1990s, the European Union began strengthening political and economic cooperation with Latin American countries. In 1997, after lengthy negotiations, Mexico finally became the first country in Latin America to sign an Economic Partnership, Political Coordination and Cooperation Agreement (Global Agreement) with the EU. Like the USMCA, the EU-Mexico Global Agreement also contains a chapter on TBT, which is substantially based on the regulations of the TBT Agreement of the WTO. The EU-Mexico Global Agreement contains provisions to promote cooperation between standard developing organisations, CABs, and accreditation bodies. The agreement provides for closer cooperation between the EU and Mexico in this area.

The parties also agreed to promote regulatory cooperation to align further technical regulations and CA procedures with international standards and recommendations. To this end, the TBT chapter includes provisions to facilitate regulatory cooperation between the EU and Mexico and comprehensive transparency provisions.

2.2 Mexico's National Quality Infrastructure System

Key points in this section:

- **Since 2020, Mexico has had a Quality Infrastructure Law.**
- **The Ministry of Economy, through the National Commission of Quality Infrastructure (Comisión Nacional de Infraestructura de la Calidad) leads and coordinates the National Quality Infrastructure Programme (Programa Nacional de Infraestructura de la Calidad).**
- **The Commission, the Programme and the Platform are the key instruments.**

The LIC[11, 12], which came into force on 31 August 2020, describes the entire system of Mexican QI. Thus, the law underlines the systemic character of QI and goes beyond the description of individual components in the previous law, the Federal Law on Metrology and Standardisation (Ley Federal sobre Metrología y Normalización - LFMN)[13]. With this legal innovation, Mexico adopts the internationally used term "quality infrastructure" and thus implicitly refers to the global cooperation framework.[14]

The LIC is divided into four books:

1. The national quality infrastructure system, including its objectives, authorities, definitions, legitimate public interest objectives, the bodies in charge of technical regulations (NOM) and the integration of conformity assessment.

2. The quality and innovation system, including the rules and the organisations entitled to standardising activities.

3. The national metrology system, referring to the competent and responsible authority for final scientific, industrial and legal metrology.

4. Provisions, including the integrated quality infrastructure technology platform, incentives, market surveillance, verification and surveillance, sanctions and resources.

The law aims to foster competitiveness, new technologies and economic development by improving the quality of production of goods and services, expanding production capacities, promoting international trade, and continuously improving value chains.

With the NOMs, the regulatory authority aims to protect legitimate public interest objectives (e.g., national security needs, prevention of fraudulent practices, protection of human health or safety, protection of animal or plant life or health, or the environment). Essentially, the law provides for creating physical and digital QI, establishing coordination and cooperation mechanisms, and improving people's quality of life.

[14] See definition of QI by INetQI,

The transitional provisions of the LICs stipulated that the Mexican government should have issued a regulation implementing the law within twelve months of it entering into force. At the time of writing, the implementing ordinance ("reglamento") is still pending. Hence, until further notice, the ordinance of the LFMN continues to apply.

Figure 1 provides an overview of Mexico's National Quality Infrastructure System, and the explanation can be found below:

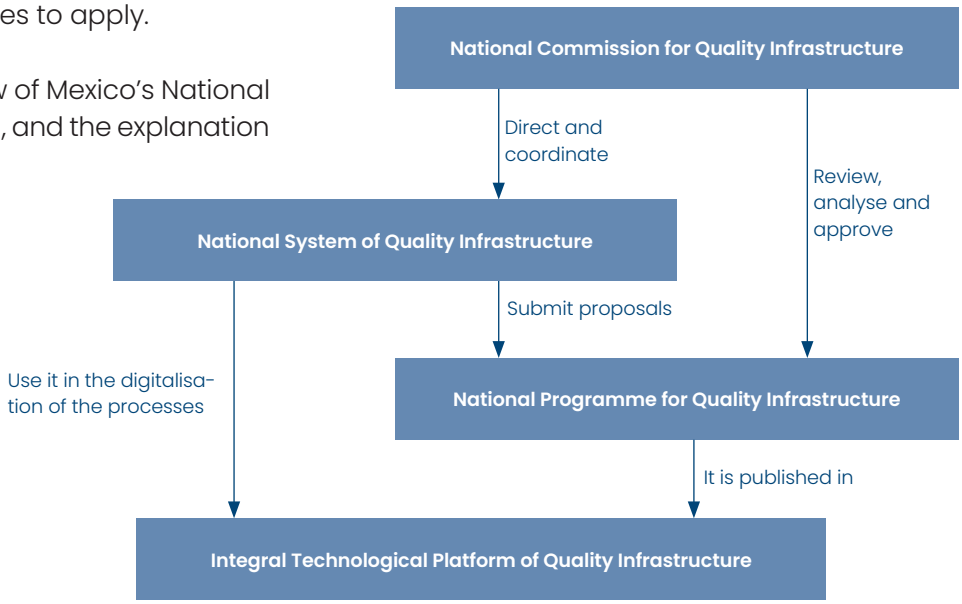

Figure 1: The new National Quality Infrastructure System. Own representation.

The Mexican Ministry of Economy (Secretaría de Economía) is the responsible authority of the entire QI system. It chairs the National Quality Infrastructure Commission (Comisión Nacional de Infraestructura de la Calidad - CNIC or Commission for short). The Commission includes representatives of ministries, technical regulation authorities, metrology, standardisation and accreditation bodies, chambers, industry and trade associations, public and private academic institutions, experts and scientists.[15] Subject to the specific provisions of the pending ordinance, the Commission formulates the policy guidelines and coordinates the national QI institutions.[16]

The Commission drafts and adopts the National Quality Infrastructure Programme (Programa Nacional de Infraestructura de la Calidad - PNIC). The programme is an instrument for planning, implementing, coordinating, and reporting on technical regulations, standardisation and metrology activities at national level. It shall be prepared annually and shall be consistent with the National Development Plan and with the sectoral programmes of the regulatory authorities.[17]

The Integral Technology Platform for Quality Infrastructure (Plataforma Tecnológica Integral para la Infraestructura de la Calidad - PLATIICA) is another central instrument of the QI system.[18] PLATIICA aims to make the management of Mexico's QI more efficient, facilitate compliance by individuals and reduce transaction costs. It replaces the previous Integrated Standards and Conformity Assessment System (Sistema Integral de Normas y Evaluación de la Conformidad, SINEC).[19]

According to some stakeholders, PLATIICA should support NOMs, standards, national measurement standards, certified reference materials, and the capabilities of measurement and calibration of CENAM and the Designated Metrology Institutes in Mexico. PLATIICA could be used for verification, monitoring and market surveillance.

[15] Article 16 of LIC. (All articles mentioned below refer to the LIC, unless another source of rights is explicitly mentioned.)
[16] Article 2.
[17] Article 29.
[18] Article 131 to 135.

QI for refrigerators in Mexico

In Mexico, the QI for refrigerators is well developed, especially to meet the high demands of export markets. At the same time, consumers in Mexico also benefit from the high quality, safety, and energy efficiency standards. The production of household appliances is concentrated in the border region with the United States. In 2019, 345 household appliance manufacturers were in the state of Nuevo Leon alone, employing 413 771 people.[20]

The Household appliance cluster (Clúster de Electrodomésticos, CLELAC) is also based in this federal state. Numerous accredited CABs are active in testing, product certification and calibration.

Figure 2 shows how the Mexican Quality Infrastructure system works together to support the quality and safety of refrigerators. The contributions of each entity are discussed below, at the end of each section.

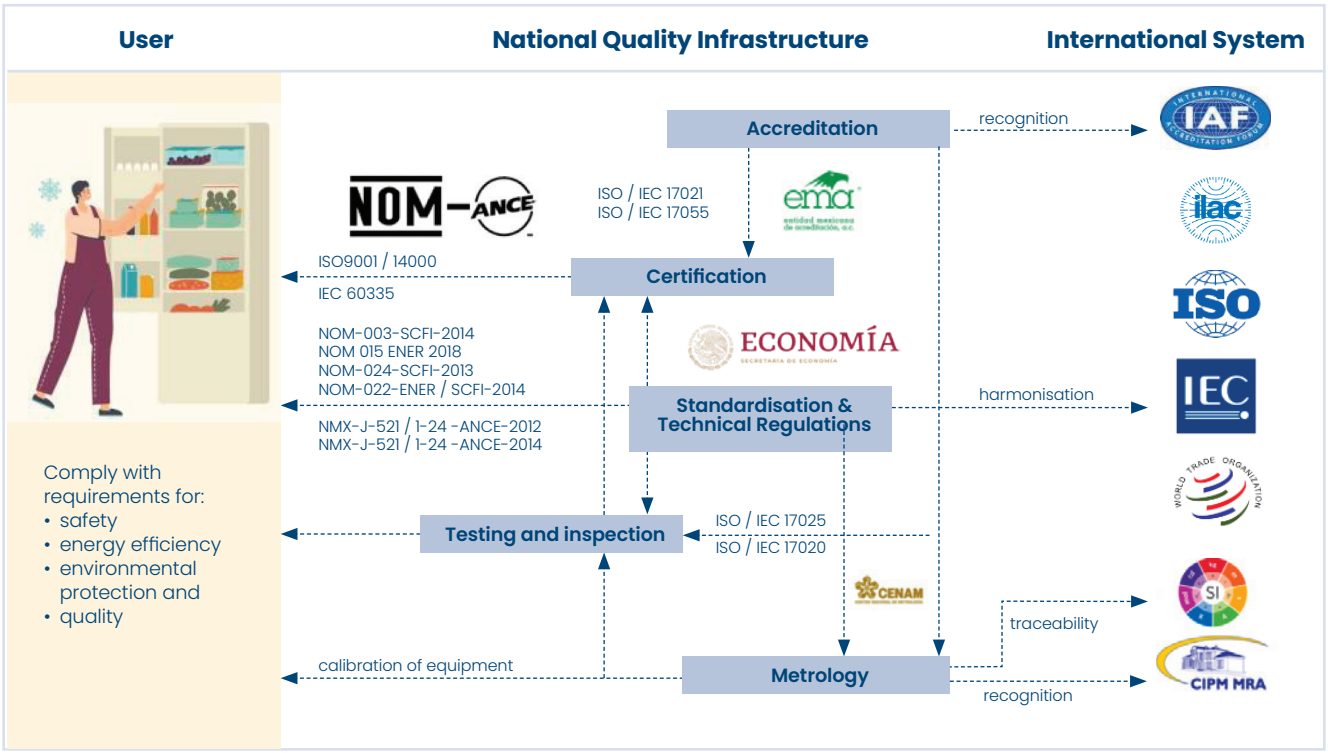

Figure 2: Quality infrastructure system for refrigerators in Mexico.
Own representation.

2.3 Components of the Mexican QI system

Businesses and consumers can use a range of services provided by the national QI. They usually obtain the services through CABs, which offer laboratory tests, certification, inspection or calibration of the measuring instruments. The accreditation bodies evaluate the technical competence of CABs, and the National Metrology Institute or the Designated Institutes provide the traceability of the measurement.

The National Standardisation Bodies ensure the adoption of international standards in the development of domestic standards. In due time, the regulatory authorities may develop technical regulations, known as Normas Oficiales Mexicanas (NOM), based on those domestic standards which are harmonised with international standards. This procedure is a way of implementing in Mexico the Technical Barriers to Trade Agreement of the World Trade Organization (WTO).

Figure 3 shows the central blocks of the National Quality Infrastructure System.

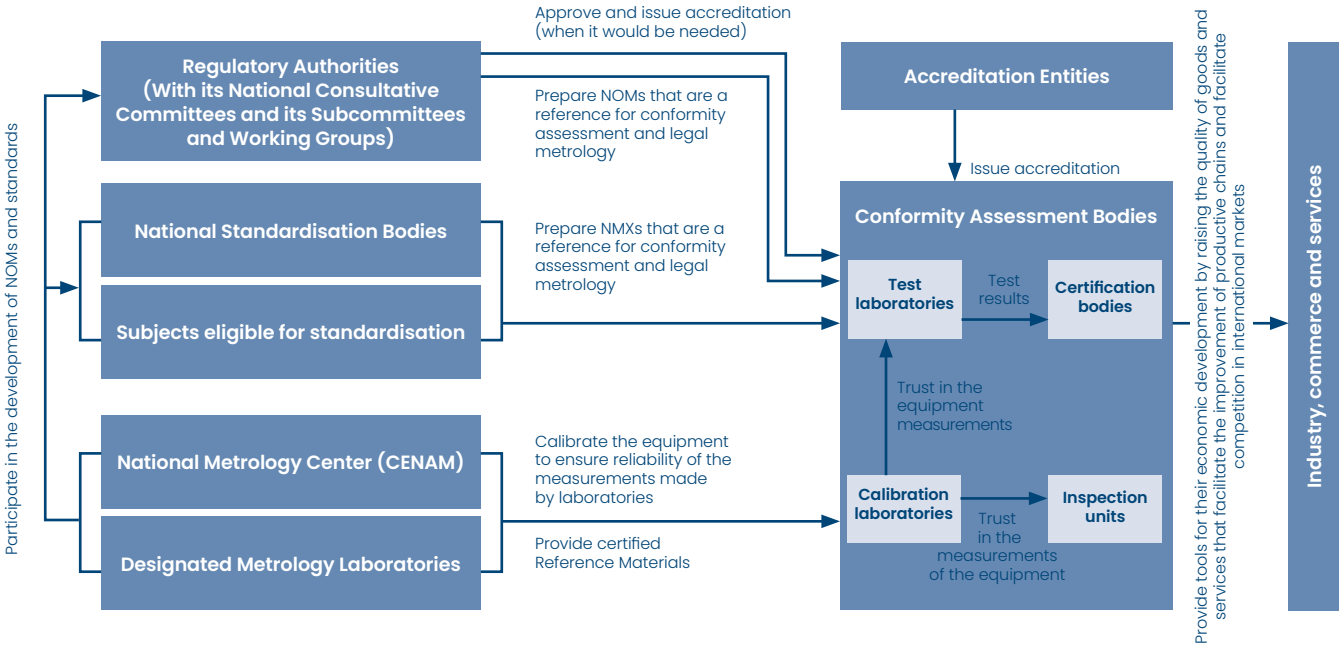

Figure 3: Systemic interaction of QI components.
Own representation.

2.3.1 Technical Regulation and Standardisation

Key points in this section:

- **Businesses and consumers are the users and beneficiaries of the QI system.**
- **NOMs are technical regulations and it is mandatory to comply with them.**
- **Technical Regulations help to protect human safety and health, animal and plant life and health, and the environment.**
- **Several private organisations may be responsible for standardisation.**
- **Foreign standardisation bodies can develop standards in Mexico to be harmonised with international standards.**
- **Technical regulations and standards will be published on the PLATIICA platform.**

Clarification of terminology

In Mexico, technical regulations are called Normas Oficiales Mexicanas (Mexican Technical Regulation - NOM) and serve to promote the quality of products and services for economic development and the protection of the legitimate objectives of public interest. On the other hand, standards (estándares - NMX) are made to promote economic growth, potentiate innovation, and increase competitiveness. It is good practice in international trade that technical regulations refer to harmonised standards. Since the enactment of the Quality Infrastructure Law in July 2020, the term "standard" is in force aiming at replacing the old term "Norma Mexicana".[19]

Technical Regulation

NOMs are documents which are mandatory to comply with and whose main purpose is to promote the protection of legitimate public interest. The regulatory authorities (Autoridades Normalizadoras) issue NOMs.

These authorities are ministries and recognised bodies of the federal public administration in charge of technical regulations.[20] NOMs are applied by the ministries and public institutions in their respective areas of competence to prevent possible damage to the objectives of the legitimate public interest.

Legitimate public interest objectives include health protection and promotion; protection of the physical integrity, health, and life of workers in the workplace; protection of organic production, genetically modified organisms, agri-food, aquaculture, fisheries, animal and plant health and safety; food safety; education and culture; tourism services; national security, environmental protection and climate change, use and exploitation of natural resources, healthy rural and urban development, public works and services, transport safety, protection of the right to information, protection of appellations of origin, and other public needs as defined by applicable law.[21]

[21] Mexico thus deviates from the translation in other Spanish-speaking countries, where the English term „standard" is translated as „norma", see Secretariat ISO/TC 176 STTG, ISO/TC 207/STTF, ISO/CASCO STWG, Spanish Translation Groups, Document ISO/CASCO STWG, N XX RX, Document ISO/TC 176 STTG, N XX RX, Document ISO/TC 207 STTF, and N XX RX; version 04/10/2018.
[22] Article 4.
[23] Article 12.

There are currently more than 700 NOMs for different regulated sectors (Figure 4). They are still governed by the LFMN and overseen by the Ministry of Economy through the DGN.

Figure 5 shows the actors involved in the elaboration of NOMs, including public bodies, technical education institutions, and companies from different sectors.

However, the lack of uniform principles combined with the breadth of topics covered contributes to a fragmented and sometimes confusing approach to using and implementing NOMs (OECD 2020).

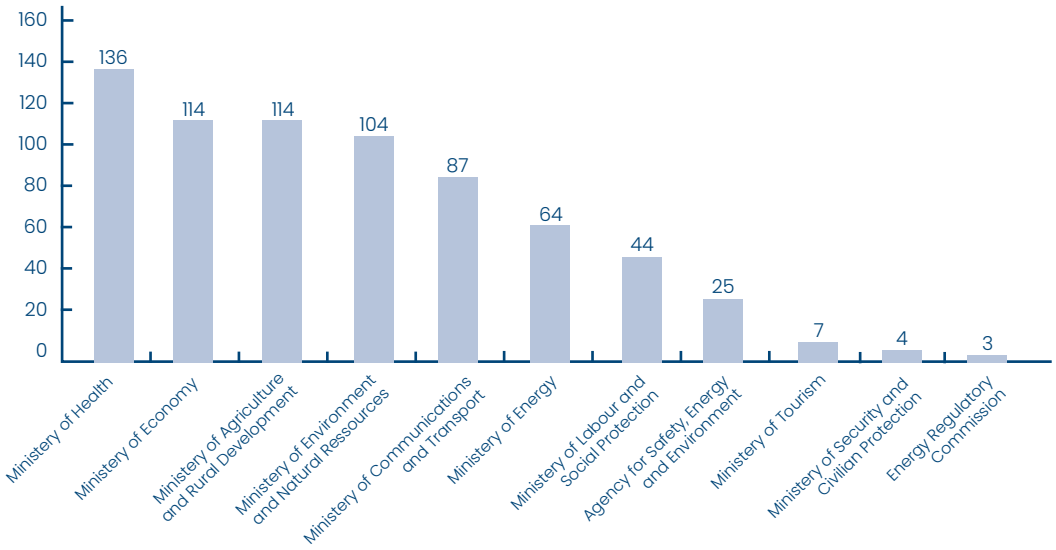

Figure 4: NOMs by Ministry or Federal Agency. Source: DGN, 2020

National bodies involved in working groups contributing to the formulation of NOMs	Development of NOMs	Metrology	Accreditation	Conformity Assessment Prosedures	Regulatory Inspection and / or market surveillance
DGN	●	●			
CONAMER	●				
Sectoral Regulators	●			●	●
CENAM		●			
EMA	●		●		
Conformity Assessment Bodies	●			●	●
PROFECO	●			●	●
Civil Society and business	●				●
Customs					●

Figure 5: Actors involved in the NOMs life cycle.
Please note that the source relies on the Federal Law on Metrology and Standardisation (LFMN), which became outdated in 2020 with the publication of the LIC. Source: OECD 2020

The National Advisory Committees for Technical Regulation (Comités Consultivos Nacionales de Normalización) are collegial bodies belonging to each ministry of the Mexican government, responsible for preparing NOM and promoting their compliance.[22] The Committees issue guidelines to incorporate the results of the Regulatory Impact Assessment (RIA) and other provisions in the General Law for the Improvement of Technical Regulation (Ley General para la Mejora Regulatoria)[23] into the regulatory process.[24] All NOM shall be published on the PLATIICA platform.[25]

Standardisation

The LIC defines a standard as "a technical document that provides for a common and repeated use of rules, specifications, attributes or test methods applicable to a good, product, process or service, as well as those rules related to terminology, symbology, packaging, marking, labelling and concordance."[26]

The DGN of the Ministry of Economy coordinates and authorises the activities of National Standardisation Bodies (NSBs; Organismos Nacionales de Normalización, ONN).[27] NSBs are legal entities whose main objective is elaborating and issuing standards in the areas registered by the DGN.

NSBs shall allow the participation of all interested sectors in the committees for elaborating standards, as well as of the regulatory authorities of the federal public administration. The work of NSBs is part of the system of quality and innovation.[28] According to the still valid directives of the LFMN,[29] the DGN publishes a list of NSBs, which include the following:[30]

1. Mexican Society for Standardisation (Sociedad Mexicana de Normalización, NORMEX).

2. Mexican Institute for Standardisation and Certification (Instituto Mexicano de Normalización y Certificación, now IMEEC)

3. Association for Standardisation and Certification (Asociación para la Normalización y Certificación, ANCE)

4. National Institute for Textile Standardisation (Instituto Nacional de Normalización Textil, INNTEX)

5. National Organisation for Standardisation and Certification in Construction (Organización Nacional de Normalización y Certificación en la Construcción, ONNCCE)

6. Electronic Standardisation and Certification (Normalización y Certificación Electrónica, NYCE)

7. Council for the Promotion of the Quality of Milk and Dairy Products (Consejo para el Fomento de la Calidad de la Leche y los Productos Lácteos, COFOCALEC)

8. Centre for the Standardisation and Certification of Products (Centro de Normalización y Certificación de Productos, CNCP)

9. National Chamber of the Iron and Steel Industry (Cámara Nacional de la Industria del Hierro y del Acero, CANACERO)

10. National Standardisation Body for Dairy Products (Organismo Nacional de Normalización de Productos Lácteos, ONNPROLAC)

The LIC stipulates that chambers, academic and research institutions, universities, associations, and other legal entities are admitted as subjects authorised to standardise in selected fields.[31] For this purpose, the interested party must apply to the DGN with the following requirements: the subject matter on which it wishes to standardise and the economic sector in which it wishes to standardise, as well as the industry or economic sector. Furthermore, the necessary legal, technical, administrative, and financial capacities must be demonstrated to develop these standards. The applicant must also confirm that they will use international standards and present their methodology.[32]

[24] Article 25
[26] Article 36.
[27] Article 80.
[28] Own translation of the definition from Article 4..
[29] In the USA, the private institution ANSI performs these functions..
[30] Articles 73 to 94.
[31] Article 72 of LFMS.
[33] Article 78.
[34] Article 92.

For a long time, the DGN had approved only Mexican standardisation bodies. However, in 2021, UL Standards & Engagement became the first foreign NSB to receive approval to develop standards for Mexico.[35]

The LIC paves the way for other foreign standardisation bodies to be recognised and active as NSB in Mexico. The Mexican government expects this to lead to a stronger transfer of technology.

Standards and technical regulations for refrigerators

Quality infrastructure services contribute to ensuring essential requirements for consumer safety and environmental protection and, secondly, to improve refrigeration appliances' performance and efficiency.
In Mexico, the National Standardisation Body ANCE is responsible for developing Mexican standards (NMX) in electrical engineering. Within ANCE-CT 61, Safety in Household and Similar Electrical Appliances is responsible for the safety of refrigerators.

There are two Mexican standards that establish the safety requirements for the refrigerator, and they are: NMX-J-521/1-24-ANCE-2012 "Household and similar electrical appliances-Safety-Part 1: General requirements", and NMX-J-521/2-24-ANCE-2014 "Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice cream makers and ice making machines".

Because a large percentage of refrigerators made in Mexico are for export, they also comply with international standards such as IEC 62552 Domestic Refrigerating Appliances - Characteristics and test methods - Part 1: General requirements, and others based on IEC 60335. The standards relevant to refrigerators can be purchased on the ANCE website.[36]

Technical regulations for refrigerators

The Ministry of Economy is the Regulatory Authority that ensures that refrigerators and other household appliances comply with safety and information requirements through the following NOMs:

- NOM-003-SCFI-2014 "Electrical Products - Safety Specifications".
- NOM-024-SCFI-2013. Commercial information for packaging, instructions, and warranties for electronic, electrical and household appliance products".
- NOM-008-SCFI-2002 "General System of Measurement Units".

Whereas, the Ministry of Energy has issued NOMs for Energy Efficiency:

- NOM-015-ENER-2012. Energy efficiency of household refrigerators and freezers. Limits, test methods and labelling.
- NOM-022-ENER/SCFI-2014, Energy efficiency and user safety requirements for self-contained commercial refrigeration appliances. Limits, test methods and labelling.

In PLATIICA, you will be able to consult the technical regulations that apply to the product.

A valuable aspect for the consumer is the interpretation of the labels accompanying the refrigerators, as it indicates the compliance of the refrigerator with the regulation. The refrigerator label shows the NOM label and the seal of the certified and approved body that has issued the certificate of compliance with the NOM. Figure 6 shows the label used by ANCE, for example.

Figure 6: NOM-ANCE label

2.3.2 Conformity assessment and accreditation

Key points in this section:

- **CABs provide services directly to companies.**
- **The LIC prescribes self-declaration and third-party CA.**
- **CABs can operate on both sides of the Mexican-US border.**
- **Mexican accreditation services are recognised internationally.**
- **More than one accreditation body operates in Mexico.**

In Mexico, CA is understood as a technical process demonstrating compliance with NOMs, and national and international standards. CA is based on the corresponding standards, particularly those of the ISO CASCO 17000 series and its national equivalents.[37]

Types of conformity assessment

The LIC mentions two forms of CA: Self-declaration and third-party conformity assessment.[38] The Table 1 clarifies the differences between the two forms:

	Self-declaration/ first party CA	Third-party CA
Scope	Limited to a specific product, service, or process	Can involve an entire management system
Performed by	Supplier or seller	Organisation independent of the seller or buyer
Reliability	Low	High
Documentation	Minimal/ Supplier declaration of conformity (SDoC)	Detailed
Independence	No	Yes
Cost	Low	High
Suitable for	Low-risk products	High-risk products

Table 1: Comparison of first and third-party conformity assessment.
Source: Own representation based on ISO/IEC 17000:2020

CA is part of QI that directly contacts companies. Its services include certification and inspection bodies, testing laboratories, medical laboratories, producers of reference materials and interlaboratory comparison providers.

Self-declaration of suppliers should apply to products that are low risk for safety, security and the environment. Such an approach would reduce the burden of monitoring NOMs and allow the authorities to concentrate on controlling the high-risk products. This means taking a stronger role in CA for the private sector.

[38] Article 46.

Conformity assessment for competitiveness and innovation

Industry, trade and services benefit from CA on a national and international level. At the national level, companies use CA to improve the quality of their products and services. CA also promotes sustainability and fosters productivity and innovation. At the international level, conformity assessment facilitates access to demanding markets and global value chains, as companies can demonstrate that they meet international requirements to compete globally.

Due to Mexico's integration into the North American Free Trade Area, Mexican industry must comply with the private industry standards required by the US market, such as the ASTM International, UL, etc. USMCA allows national bodies to contract foreign CABs. In the border area, there are currently already Mexican CABs accredited by US entities for the calibration of equipment testing force, pressure, and hardness. Through mutual recognition between US and Mexican bodies, CABs can operate on both sides of the border.

Accreditation

The conformity assessment bodies demonstrate their technical competence and independence through accreditation.

The Mexican system for accreditation was introduced in 1992 with the LFMN and updated in the LIC.[39]

The law allows private non-profit organisations to act as accreditation bodies. To operate as an accreditation body in Mexico, authorisation by the DGN is required.[40] Following the model of the United States of America, in Mexico, several accreditation bodies (ABs) are authorised and active. Currently, there are three privately run, non-profit accreditation bodies:

- ema (Entidad Mexicana de Acreditación)
- MAAC (Mexicana de Acreditación A.C)
- SIAAC (SIIAC Sociedad Internacional de Acreditación A.C.)

The ema started its operations in January 1999 with the approval of the then Ministry of Trade and Industrial Development (SECOFI) and under the then LFMN. It was founded as a non-profit civic association and was the first privately run accreditation body in Mexico and the only one in the country for 21 years.

ema is a signatory to most of the Multilateral Recognition Arrangements (MLA) of the International Accreditation Forum (IAF), the Mutual Recognition Agreements (MRA) of the International Laboratory Cooperation (ILAC) and the Interamerican Accreditation Cooperation (IAAC), and has a good international reputation.

[39] Article 49 to 52.
[40] Article 52

Table 2 shows the number of CABs accredited by the ema until 2021.

Scope	Level 2	Level 2	MLA/MRA	Accredited CABs[41]
IAF MLA	Product Certification	ISO/IEC 17065:2012	09/10/04	119
	Management System Certification	ISO/IEC 17021-1:2015	See footnote[42]	223
	Person Certification	ISO/IEC 17024:2012	N.A.	10
	Validation and Verification	ISO/IEC 17029:2019	N.A.	
	Greenhouse Gases	ISO 14065:2013	26/10/18	18
ILAC MRA	Testing	ISO/IEC 17025	17/11/05	2138
	Medical Laboratories	ISO 15189	17/11/05	182
	Calibration	ISO/IEC 17025	17/11/05	1069
	Inspection	ISO/IEC 17020	24/10/12	3063
	Proficiency Testing	ISO/IEC 17043	21/10/19	27
	Reference Material Production	ISO 17034	23/06/21	7
	Biobanking Facilities	ISO 20387:2018	N.A.	

Table 2: Data on accredited CABs in Mexico by ema.
Source: Mesopartner/ GQII

MAAC was approved as an accreditation body on 6 May 2020 to provide accreditation services to management systems certification bodies. On 8 October 2021, it received approval from the DGN to extend its scope to accreditation inspection bodies, testing and calibration laboratories and product certification bodies. In mid-2022, MAAC accredited 4 certification bodies for and 5 for management systems, 6 testing and 3 calibration laboratories, and 24 inspection bodies. MAAC is a full member of IAAC.

SIAAC was recognised on 14 October 2021 as an accreditation body. Currently, SIAAC provides accreditation services to certification bodies for management systems, products, processes and services, and personnel. It can also accredit inspection bodies. By mid-2022, SI-AAC had accredited its first product certification body. On April 1, 2022, the IAAC General Assembly approved the associate membership application of SIAAC. The LIC foresees that a list of accreditation bodies and CABs will be published on the PLATIICA Platform.[43]

[41] Collection date 18/08/20
[42] Food Safety ISO 22000:2018, 2005 (FSMS) 21.10.15, QMS ISO 9001:2015 (QMS) 03.11.01 Environmental ISO 14001:2015 (EMS) 09.10.04, Information Security ISO/IEC 27001:2013 (ISMS) 11.08.17 Energy ISO 50001:2018, 2011 (EnMS) 05.04.18, Medical Devices ISO 13485:2016 (MDMS) 05.04.18 and Occupational Health and Safety ISO 45001:2018 (previously OHSAS 18001) 20.05.20.
[43] Article 44

Conformity assessment for refrigerators

The manufacturers of household appliances in Mexico are strongly oriented towards exports to the USA. Consequently, they use third-party conformity assessment to certify and test the relevant Mexican technical regulations and private standards. In Mexico, there are the following CABs:

- About 20 Certification Bodies accredited according to NOM-003-SCFI-2014 "Electrical Products-Safety specifications", which applies to refrigerators.
- 6 Certification Bodies accredited under NOM-022-ENER-SCFI-2014 "Energy efficiency and user safety requirements for self-contained commercial refrigeration appliances. Limits, test methods and labelling".
- More than 20 accredited Testing Laboratories that can perform safety tests on refrigerators. These include, for example, electrical shock hazards, mechanical hazards (e.g. fan blockages), and fire hazards.

The information on the accredited CABs and the scopes can be found on the website of the accreditation bodies.[44]

[44] See ema, MAAC, SIAAC

2.3.3 Metrology

CA is part of QI that directly contacts companies. Its services include certification and inspection bodies, testing laboratories, medical laboratories, producers of reference materials and interlaboratory comparison providers.

- Metrology is an integral part of the National System of QI.
- The LIC gives some responsibilities to CENAM in the area of Legal Metrology.
- CENAM and DI guarantee traceability to the International System.
- CENAM has 72 national measurement standards and provides about a hundred Certified Reference Materials.
- Key players in industrial metrology are the calibration laboratories, which provide the service directly to the industry and users.

The use of metrology has a direct impact on the quality of products and services, the profitability of industries, and confidence in business transactions. For small and medium-sized enterprises, poor and missing calibration of their measuring instruments can lead to high rejection rates and expensive returns from customers. Metrological competences, on the other hand, help to strengthen the innovative power of companies.

Metrology is an integral part of the National System of QI. Metrology aims to ensure the uniformity and reliability of measurements performed in the country as well as their comparability with other countries.[45]

The metrology system is divided into three parts:

- Scientific metrology
- Legal metrology
- Industrial metrology

[45] Article 95

The Metrology System

The Organization of American States (OAS) and the free trade plans in the Americas have played an essential role in developing the Mexican metrology system, which addresses measurement issues in Mexico. When the North American Free Trade Agreement (NAFTA) was signed, participating countries were required to have intellectual property protection structures and effective standards and measurement systems. These requirements led the Mexican government to create the National Metrology Centre (CENAM).

CENAM was officially inaugurated on 29 April 1994 under the framework of the Federal Law on Metrology and Standardisation of 1 July 1992. With the establishment of CENAM, Mexico filled a technological gap, as its trading partners, the USA and Canada, had long had their own NMIs.

Today, CENAM is Mexico's NMI with a strong technical reputation in the Americas.[46] This institution owns legal personality and assets. It is subordinate to the Mexican Ministry of Economy. Its mission is to carry out scientific research and technological development in the field of metrology and its applications to contribute to the welfare of society and inclu sive economic development. CENAM represents Mexico at the International Bureau for Weights and Measures (BIPM).

Designated Institutes

Other institutions of the metrology system are the Designated Institutes (DI) and the calibration laboratories. DIs are public bodies and represent Mexico for specific measurement areas at the International Committee of Weights and Measures. They are responsible for establishing selected national measurement standards and the provision of metrological services.[47] Current Designated Institutes are the National Institute of Ecology and Climate Change (Instituto Nacional de Ecología y Cambio Climático, INECC) for ozone concentration in ambient air and the National Institute of Nuclear Research (Instituto Nacional de Investigación Nuclear, ININ) for ionising radiation.[48]

Calibration laboratories

A National Calibration System was created within the framework of the LFMN (Article 24). Its objective

was to ensure the uniformity and reliability of measurements carried out in the country, both in commercial transactions and services, industrial processes, and related scientific research and technological development work. The LIC does not explicitly mention a National Calibration System. Nevertheless, the 1069 accredited calibration laboratories accredited in 2021 by ema[49], and the accredited calibration laboratories accredited through foreign bodies can be attributed to this system.

CENAM and Designated Institutes guarantee traceability to the International System. They also calibrate the measurement standards of calibration laboratories that provide calibration services to the industry and users in general. Sometimes industry metrology laboratories also send their standards directly to CENAM for calibration.

Scientific metrology

Scientific metrology, as indicated in the LIC[50], covers the establishment of national standards of measurement and certification of reference materials, the updating of the General System of Measurement Units, scientific research and technological development in metrology, and participation in the Mutual Recognition Agreement of the International Committee of Weights and Measures.

Together with the DI, CENAM is responsible for establishing and maintaining the National Standards of measurement and Certified Reference Materials, as well as other functions indicated in the LIC, such as updating the General System of Units of Measurement; scientific research and technological development in metrology, as well as participating in the Mutual Recognition Arrangement of the International Committee of Weights and Measures.

Currently, CENAM has 72 national measurement standards in electrical metrology, physical metrology, mechanical metrology, and materials metrology (chemistry), and provides about 100 Certified Reference Materials for optical properties, substance quantity and physico-chemical properties. There are also 5 national measurement standards from the National Institute of Nuclear Research and one from the National Centre for Environmental Research and Training, both DI.

It should be noted that when sufficient certified reference materials do not exist in Mexico, the Ministry of Economy will authorise the use of reference materials produced by third parties as indicated in LFMN, and having received the prior opinion of CENAM or the Designated Metrology Institutes. Regarding the updating of the General System of Units of Measurement, CENAM, being an active member of the CIPM (International Committee of Weights and Measures), participated in the meetings for the recent revision of the new definition of the kilogram, ampere, kelvin and mole and also initiated actions to make the appropriate changes to the General System of Units of Measurement to these new definitions.

In terms of international participation, CENAM has participated in multiple key comparisons promoted by the CIPM and supplementary comparisons organised by the Inter-American Metrology System (Sistema Interamericano de Metrología, SIM). The results of these comparisons allow the Calibration and Measurement Capabilities (CMC) to be accepted internationally.

In Mexico, the relationship between CENAM and the Designated Institutes with Conformity Assessment Bodies (CABs) is aimed at maintaining the traceability of measurements. This is achieved through the upkeep of measurement standards against which the measurement equipment and instruments used for testing, calibration, and general measurements are calibrated.

This, in turn, enables laboratories, inspection bodies, and companies to perform precise measurements that can be compared with those of trade partners in other countries. The accreditation of calibration laboratories and peer evaluation within the Interamerican Metrology System (SIM) play a crucial role in ensuring the traceability of all measurements in Mexico.

[46] Article 104 – 112
[47] Article 113 – 115
[49] In 2022, MAAC started accrediting calibration laboratories and had accredited four by the end of the year.
[50] Article 95 – 103

Legal metrology

As specified in the LIC[51], CENAM has been tasked with overseeing the collaboration with Regulatory Authorities concerning metrology, with the objective of ensuring a legal oversight of measurement instruments used in commercial transactions, healthcare, environmental protection, and public safety. This responsibility encompasses activities related to the legal metrological control of measuring instruments, ensuring the adherence to NOMs and legal metrology regulations. To facilitate this, the specific mandatory measuring instruments are published in the Official Gazette of the Federation (DOF).

CENAM is now responsible for creating the scientific-technical basis for legal metrology and coordinating the types and model approvals. It participates in elaborating NOMs and Standards that establish the metrological requirements for measuring instruments subject to legal control.
So far, Mexico is a correspondent member, not a full member of the International Organization of Legal Metrology (OIML) and is currently represented by the DGN. In line with the transfer of competencies in the field of legal metrology, the DGN plans to transfer the representation of Mexico at the OIML to CENAM.[52]

Industrial metrology

Industrial metrology comprises the metrological assurance practices that the industry considers in its processes. Several factors are involved in metrological assurance, such as the methods and procedures used to measure, the competence of personnel, and the traceability of the measurement results of their measuring equipment and standards.

Traceability is a special term to express that the result of a measurement has a known relationship to the highest reference in the country, i.e., to the values of the corresponding national standards, since they are experimental realisations of the definitions of the International System of Units (Système international d'unités, SI). In colloquial terms, traceability is a property of a measurement result that makes it possible to trace it back to the SI and ensure that the results of a measurement are close to the value of the corresponding national standard within the corresponding measurement uncertainty.

Industrial metrology has been the element upon which CENAM has been built, as industry naturally demands services to meet its needs. A high percentage of CENAM's income comes from services provided to the industry.

Figure 7 shows the unbroken chain of metrological measurements: from measurements in industry and commerce, using accredited calibration services, to national standards and their relation to the SI.[53]

The industry is responsible for ensuring the traceability of the measurements they make to contribute to the reliability and uniformity of the measurements, coordinating when necessary with the CENAM, the DI, the CABs, and the Regulatory Authorities.

Productive industries may also participate in the development of metrology-related standards. In response to the industry demand, CENAM and DI then provide calibration services for measuring equipment, certified reference materials (CRM), model or prototype approval services, reports, and authorise measurement traceability to measuring standards abroad.

The calibration laboratories are key players in industrial metrology, which provide the service directly to the industry and users. Calibration laboratories are accredited in the areas of acoustics, vibration and ultrasound; specific analysers; density, dimensional, hardness, electrical, medical equipment, flow, force, humidity, impact, magnetism, mass, special measurements, optics, torque, pressure, ionising radiation, temperature, time and frequency, viscosity and volume.

[51] Article 116 – 127
[52] According to information from the interview with the Director General of CENAM.

Metrology for refrigerators

In Mexico, CENAM and the Designated Metrology Standards maintain active and internationally recognised activities in the CIPM-MRA aimed at ensuring the comparability of measurements carried out in the country against those performed in other countries. In the case of the measurements involved in the manufacture of refrigerators, CENAM has internationally recognised calibration and measurement capabilities for electricity, dimension, pressure, force, mass, temperature, and humidity. The NMI maintains national standards for the following quantities, measured in the manufacture and testing of refrigerators:

- Electrical quantities
- Dimensions
- Temperature
- Humidity

The corresponding CMC calibration measurement capabilities are recognised through the CIPM.

Mexico has accredited calibration laboratories that perform instrument calibrations on these requested measures. These laboratories are in different parts of the country and are particularly concentrated in the border region with the United States of America.

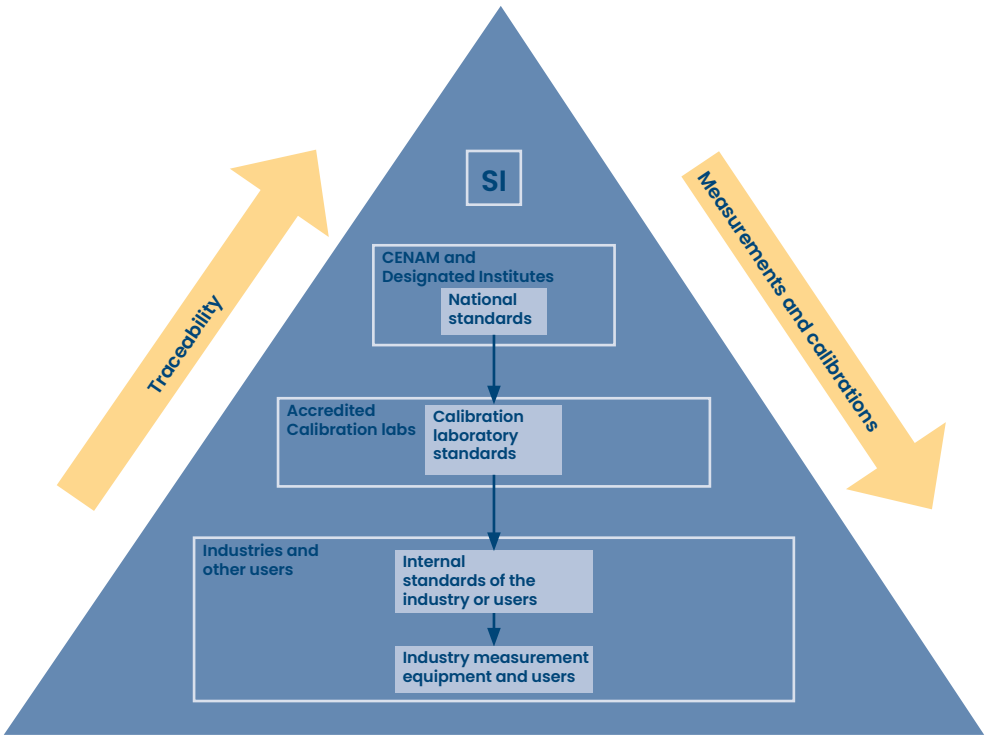

Figure 7: The pyramid of measuring traceability to measuring standards abroad. Own representation.

2.3.4 Market surveillance

Key points in this section:

- **Market surveillance is used to ensure compliance with the NOM.**
- **More than twelve public bodies are responsible for market surveillance.**
- **Mexico plans to introduce a risk-based market surveillance programme.**

Market surveillance is used by competent authorities to ensure compliance with the Technical Regulations (NOM).[54] The government authority in charge of a specific NOM is also responsible for its supervision, including developing a market surveillance programme. The LIC sets out the requirements for inspection visits, and regulate NOM market surveillance activities.

According to the allocation of the protection competencies to different ministries and public institutions, the competencies for market surveillance are also distributed. A study by the OECD identified 708 valid NOMs in 2018 (OECD 2020), for which more than a dozen different institutions are responsible.

The Federal Consumer Protection Agency (Procuraduría Federal del Consumidor PROFECO) market surveillance activities mainly respond to consumer protection. PROFECO is also responsible for monitoring legal metrology and proactively monitors compliance with the NOM for fuels, scales and weights. So far, PROFECO does not follow a risk-based approach to market surveillance. Mexican companies successfully meet the requirements in export markets (automobiles, household appliances and textiles). In contrast, market surveillance authorities often need help to monitor the domestic market systematically. PROFECO reports, for example, that around 20% of the products marketed in Mexico do not meet the requirements of the Technical Regulations (NOM). In some economic sectors, this applies to 50% of the products.

The overall goal of the LIC is to enforce a culture of compliance. This requires, for example, a reorganisation and better coordination of responsibilities for market surveillance. At the same time, a risk-based approach to market surveillance is being planned, through which inspection activities can focus on critical areas for safety, health and the environment.

[54] A detailed description and analysis of market surveillance in Mexico can be found in Chapter 3 of the OECD study „Implementing Technical Regulations in Mexico.

Market Surveillance for refrigerators

Market surveillance of the refrigerator market in Mexico is carried out by requirement of the Ministry of Economy:

- Periodically at the plants of the companies that manufacture them, and
- Randomly, a product offered in the shops for sale can be taken for testing.

Additionally, PROFECO conducts quality studies to provide consumers with information on product performance, characteristics, and functions. The study on domestic refrigerators was published in the March 2018 Consumer Magazine (Revista del Consumidor). It considered 18 models of 9 different brands of refrigerators taken in a sampling period from December 2017 to January 2018 and with an analysis period from 10 January to 22 March 2018.

A total of 240 tests were carried out concerning the following Technical Regulations and Standards:

- NOM-024-SCFI-2013 "Commercial information for packaging, instructions and warranties for electronic, electrical and household appliance products".
- NOM-015-ENER-2012 "Energy efficiency of household appliances refrigerators and freezers. Limits, test methods and labelling".
- NOM-008-SCFI-2002 "General System of Measurement Units".
- NMX-J-521/1-ANCE-2012 "Household and similar electrical appliances - Safety - Part 1: General requirements".

  NMX-J-521/2-24-ANCE-2014 "Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice cream
  makers and ice makers".

As a result, it was confirmed that all the analysed refrigerators operate as specified by the manufacturer and present the complete information required by the national regulations in force.

3. The German QI SYSTEM[55]

3.1 Context and framework

Key points in this section:

- **Germany is a federal and a European Union member state.**
- **Germany's economy is the largest in Europe.**
- **Social and environmental standards need to be met in global supply chains.**

Federal State and European Single Market Integration

The Federal Republic of Germany (henceforth Germany) is a federal state and a founding member of the European Union. The trade and market regulation competencies are distributed between the European, Federal and State levels. The competencies for regulating the European internal market and international trade lie with the EU. The sixteen federal states are responsible for implementing market surveillance, and the Federal Government assumes mainly coordinating functions.

Germany is the largest economy in the EU

Germany's economy is the largest economy in Europe and the fourth largest in the world.[56] The service sector domi nates the economic structure, although the industrial sector is also strong. The automotive, commercial vehicle, electrical engineering, mechanical engineering, and chemical industries are the most competitive industrial sectors worldwide. In the service sector, exports are dominated by the information technology and communications industries.

SMEs enterprises are the success factor of the German economy. The "German Mittelstand" has become an international trademark,[57] with a disproportionately large number of "hidden champions" coming from Germany. They produce highly specialised and innovative products and solutions in close contact with their global customers. Their recipes for success are top quality, with a high degree of vertical integration and concentration on their competencies.

European legal QI system framework

The legal framework and the institutions dealing with QI are decided upon not only at the national level but also in line with EU level and international agreements, e.g. as part of the technical harmonisation of the European Single Market or under the Agreement on TBT administered by the WTO. Germany and the EU have both been WTO members since 1995.[57]

In the area of technical regulations, the framework of the European internal market is authoritative. The QI system harmonised in the EU is firmly linked to the success story of the European Single Market. Citizens can rely on equally high product standards in the EU. Manufacturers must only declare their products' conformity with the legal EU product requirements once, not in each member state. The so-called harmonised standards, commissioned and developed by the EU Commis sion at the European Standardisation organisations after approval by the EU Standardisation committee, do give the manufacturers the necessary guidance.

If the manufacturer applies harmonised standards, there is a presumption of conformity, i.e., it is assumed that the product complies with the legal requirements. If the manufacturer - depending on the product with the involvement of a third party – issues such a declaration of conformity, in each case visible using the familiar CE mark, there is usually no need for state certification. This accelerates the conformity assessment process, establishes security, and increases competition.

[55] A detailed description of the quality infrastructure in Germany can be found in the GPQI study „United in Quality and Safety"
[58] See and .

3.2 National quality infrastructure in Germany[59]

Key points in this section:

- **BMWK is the system coordinator, and Federal states are implementers.**
- **The legal framework and the institutions dealing with QI are decided in line with EU-level and international agreements.**
- **The European internal market framework is authoritative for technical regulations.**

Long trajectory but new term

Although institutions such as the German National Metrology Institute (Physikalisch-Technische Bundesanstalt - PTB) and the German Institute for Standardisation (Deutsches Institut für Normung - DIN) can look back on a history of over a hundred years,[60] the concept and understanding of a national QI system are more recent.

The BMWK has been using the term "quality infrastructure" since around 2012 to describe the systemic interaction of the independent institutions for metrology (PTB), Standardisation (DIN and DKE) and accreditation (DAkkS) that it supervises.[61] With this, Germany adopted a term that became increasingly established internationally.

[59] A detailed description of the German QI system can be found in the GPQI publication „United in Quality and Safety",

[60] PTB's predecessor, the Imperial Physical-Technical Institute (Physikalisch-Technische Reichsanstalt - PTR) was founded in Berlin in 1887 based on the initiatives and ideas of Werner von Siemens and Hermann von Helmholtz. DIN continues the work of the Standards Committee of German Industry (Normenausschuss der deutschen Wirtschaf - NADI), founded in 1917. On the other hand, the German Accreditation Body (Deutsche Akkreditierungsstelle GmbH - DAkkS) was only formed in 2010 as a uniform body of the Federal Government, the Länder and the Federation of German Industries (Bundesverband der Deutschen Industrie, BDI) following Article 4 (1) of EC Regulation No. 765/2008.

[61] A description of quality infrastructure and its national and international significance can be found, for example, in the article written by Dr Florian Thiel and Maria Loy (Department Accreditation, Metrology, Technical Supervision PTB and BAM) in the BMWi Monthly Report 12-2012.

BMWK is system coordinator and Federal states implement

The BMWK is the competent authority and simultaneously the supervisory authority for various

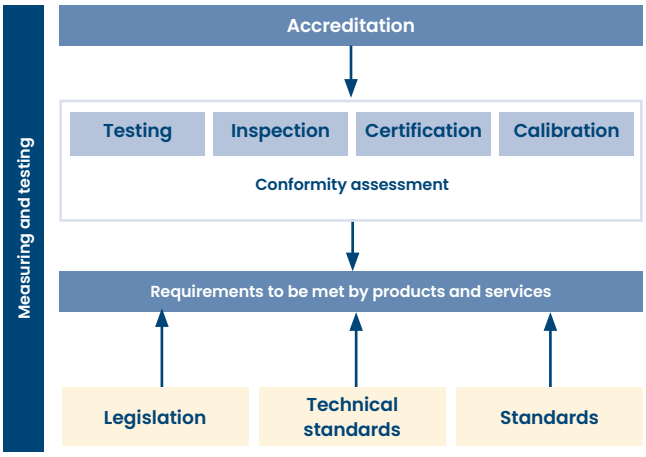

Figure 8: Functions and components of the German QI-System. Source: BMWK[63]

German QI bodies. At the same time, the Federal States have their competencies in regulation and market surveillance. The BMWK assumes a coordinating and moderating function in the system.

In the QI system, private and state actors jointly develop standards and processes for product safety. The state sets the legal framework and monitors compliance with the rules. The design of the details and its implementation are in the hands of the respective experts from private and state institutions. The interplay of public and private actors creates reliability and offers sufficient flexibility for innovation and the complexity of economic processes. The BMWK is responsible for German QI policy across all disciplines. Sectoral ministries are also responsible for QI in individual sectors.

Key QI system actors

QI key actors are the DIN, the German Commission for Electrical, Electronic & Information Technologies in DIN and VDE (Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE - DKE), the DAkkS and the market surveillance authorities at the federal and state levels. In addition, the Federal Institute for Materials

Research and Testing (Bundesanstalt für Materialforschung und -prüfung - BAM), the Federal Network Agency (Bundesnetzagentur - BNetzA) and the PTB are part of the BMWK. Many experts from companies and associations and other interested parties are involved in the Standardisation committees of DIN and DKE and dialogues at European and international levels.

German QI's legal framework

Germany has no overarching QI law. The German QI's legal framework comprises its laws, regulations, and agreements that regulate the functioning of the central system components of standardisation, metrology, and accreditation. In the field of metrology, the Metrology and Verification Act (Mess- und Eichgesetz - Mess-EG) applies, which defines the requirements to be met by measuring instruments to comply with state of the art technology to ensure correct measurement results and measurements. The Accreditation Body Act (Akkreditierungsstellengesetz, AkkStelleG) brings the corresponding EU regulation - that there may only be one accreditation body per member state - into national law.

Due to the voluntary nature of standardisation, there is no standardisation law, but a binding contract ("Bund-DIN-Vertrag") in which DIN and DKE commit to taking the public interest into account in their standardisation work to ensure that these can be used as descriptions of technical requirements in legislation and legal transactions, and to guarantee fair procedural guidelines to enable the participation of SMEs.[64]

QI for refrigerators in Germany

The German home appliance market is a mature and dynamic market. The market typically depends on replacement sales due to either damage to the existing product or consumer interest in switching to a new product format.

Germans' environmental awareness drive the market for the sale of environmentally friendly appliances. Consumers pay particular attention to user-friendliness, environmental friendliness, lower energy consumption and reasonable costs when selecting products.[65]

Figure 9 shows how the German quality infrastructure system supports refrigerator quality and safety.

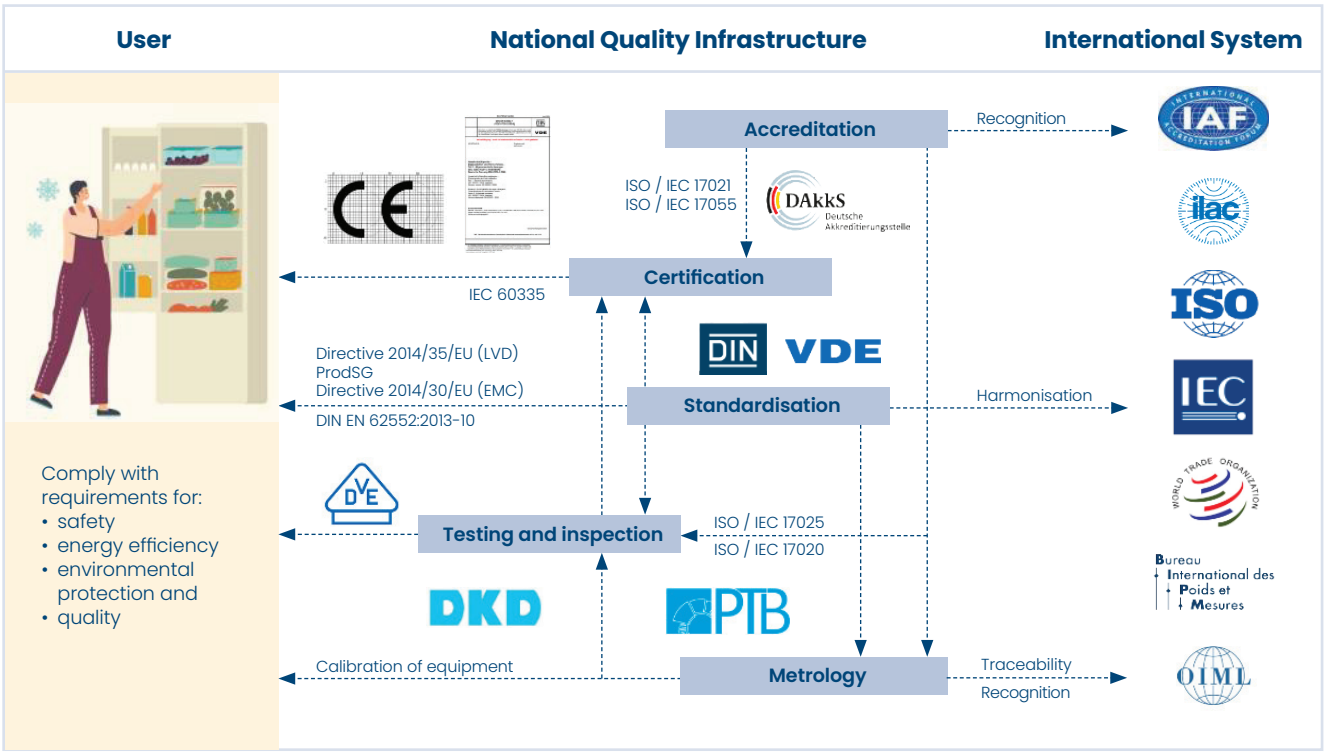

Figure 9: Quality infrastructure system for refrigerators in Germany. Own representation.

3.3 Components of German Quality Infrastructure

3.3.1 Technical Regulation and Standardisation

Key points in this section:

- **Although voluntary, harmonised European standards are tools that support EU legislation.**
- **Standards can be used voluntarily and are developed by stakeholders (private sector).**
- **The German Standardisation organisations, DIN and DKE, act according to the Standards Agreement of 1975 on behalf of the Federal Republic of Germany, as national standards bodies.**
- **DIN and DKE recognise the primacy of international standards and are active contributors to international Standardisation.**

The system of product legislation in the EU and Germany

In the area of technical regulations, the framework of the European internal market is authoritative. The legal framework is based on the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU). Subsequently, regulations, directives and decisions of the European Union are binding for the European member states. They must adapt their national legislation to the European legal requirements.

If there is a conflict between legal acts that regulate the same matter, the higher legal act establishes the framework for the lower one; and the more specific legal act takes precedence. This means more specific sectoral legislation comes before more general legislation, such as General Product Safety Directive 2001/95/EC.

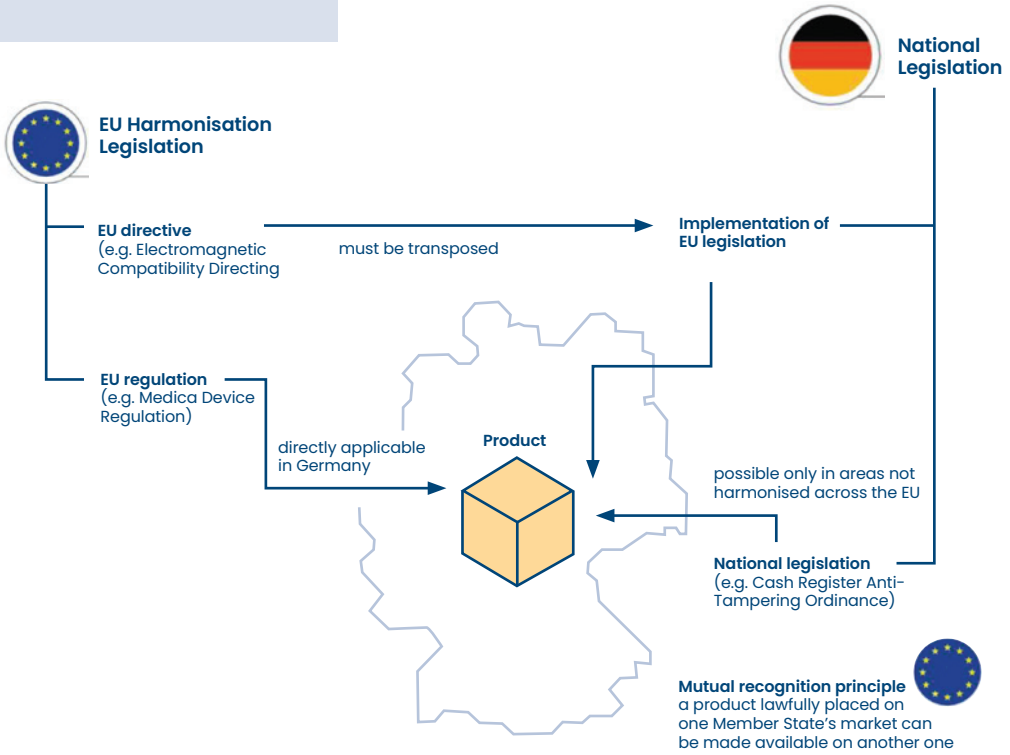

Figure 10: Relationship between EU harmonisation legislation and national rules. Source: BMWK/ GPQI 2021, United in Quality and Safety

From detailed technical requirements to modern and effective governance

In 1985, the European Union introduced the New Approach to technical harmonisation. The previous system of detailed technical specifications and regulations had become an obstacle for companies to compete successfully in the accelerating international technological competition. In the current system, the regulating institutions limit themselves to defining basic requirements and leave it to the private sector to develop the technical standards, which are harmonised throughout Europe. Technical regulation then refers in turn to the harmonised standards. When entering the market, companies are obliged to prove the conformity of their products and services themselves.

Strengthening the EU single market for goods: the New Legislative Framework

In 2008 the EU refined its system further with the introduction of the New Legislative Framework (NLF). The NLF is a set of legal acts to complement and strengthen the EU's approach to product legislation of the single market. The NLF continues the proven method that combines essential requirements and harmonised standards introduced through the New Approach. The NLF strengthens the overall coherence and consistency of EU legislation, the notification process, accreditation, conformity assessment procedures, and market surveillance.

Standardisation landscape in Germany

The German Standardisation Institution DIN is a private institution based on the self-initiative and self-administration of industry and organises standardisation. Its legal form is a non-profit association. Electrotechnical Standardisation takes place at DKE, which is a division of VDE. VDE is one of Europe's oldest and largest technical-scientific associations, developing standards since the end of the nineteenth century.

Through a contract with the BMWK, DIN - together with DKE – is the official standardisation organisation and represents Germany in the European and international standardisation organisations. The private-public partnership obliges DIN to consider the public interest and to apply fair procedures. This means that all interested groups participate in the standardisation committees on an equal footing.

The government can participate as a stakeholder in the standards development process. Regulatory authorities in turn use DIN standards as references for their technical regulations and in tendering procedures.

Open and participatory Standardisation process

The principles of standardisation work in Germany are laid down in a standard: DIN 820. All interested parties can participate in the technical committee to develop a draft standard. At DIN, committee members are required to pay a fee to cover DIN project management costs. Committee members can be informal members of DIN or DKE/VDE. A draft standard is developed in consensus with all members involved and published for public comment. DIN publishes and reviews a standard at least every five years.

Because of the increasing speed of technological developments, DIN and DKE created specifications which can be developed faster than standards: DIN SPEC and VDE SPEC (specifications). Different from standards developed, these specifications only require the participation or full consensus of some interested parties. With a DIN SPEC, a specification can thus be created relatively quickly to describe a technology that has not yet been standardised. This can be in the interest of a quick market introduction of such a technology. DIN ensures that the DIN SPEC does not collide with existing standards and publishes it internationally. The development of SPECs is funded by BMWK.

Standardisation Panel

The German Standardisation Panel (DNP) is an annual survey of companies about standardisation.[66]

In 2012, DIN and the Chair of Innovation Economics at the Technical University of Berlin initiated the project. In 2016, BMWK assumed the patronage of the DNP.

The DNP raises awareness of standardisation and its benefits among the business community. At the same time, it creates a comprehensive database for all those responsible for standardisation policy and interested parties to analyse current activities and future trends. Topics such as electromobility or Industry 4.0 are eloquent examples of their cross-sector and cross-industry demands.

The DNP is structured so that long-term observations are carried out, and current trends are considered. To achieve this, the survey within the framework of the German Standards Panel is divided into a "core questionnaire" and a "top icoriented" questionnaire. Figure 11 shows the heuristic structural model of the standardisation panel survey.

Process of developing harmonised European standards

The European Commission uses harmonised European standards to support EU harmonisation legislation. Harmonised standards are developed based on a Standardisation request from the European Commission. Even though their reference is published in the Official Journal of the EU (OJEU), the use of harmonised standards is entirely voluntary. Manufacturers may use any other technical approach to demonstrate compliance with essential requirements in the legislation. However, only by applying harmonised standards cited in the OJEU, can manufacturers benefit from the presumption of conformity.

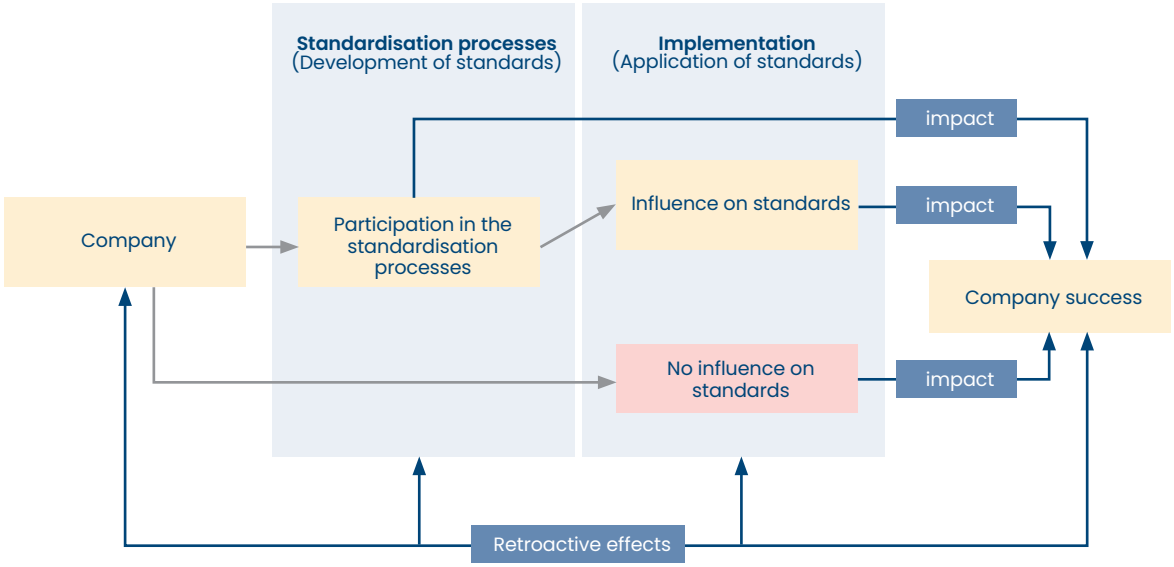

Figure 11: Model of the standardisation panel
Source: https://www.normungspanel.de/en/

Manufacturers can use harmonised standards listed in the OJEU, which eases compliance requirements. One consequence of this is a reduction in documentation requirements. On the EU website, it is possible to find an overview of standards by sector and by product, which can be used for the presumption of conformity.[67]

[67] The list of standards is available at .

Technical regulations for refrigerators in Germany

In Germany, the EU principle applies that the manufacturer is responsible for compliance with the technical regulations. An overview of the different technical rules that apply to a specific product is provided by the EU helpdesk Access2Markets.[68] Here, you can search for the relevant information by product name or HS code. Additionally, all EU member countries have product contact points, which businesses can contact for information on national technical rules and administrative procedures.

Germany's product contact points are:

- Federal Ministry of Labour and Social Affairs (BMAS), Division III Labour Laws and Occupational Safety and Health
- German Standardisation Institute (DIN)

For placing on the European Single Market, the manufacturer of a refrigerator must comply with the technical regulations from the following EU directives in the areas of safety, health and environmental protection:

Safety

- Low voltage electrical equipment. Directive 2014/35/EU (LVD) mandates essential requirements for low-voltage electrical equipment (i.e. between 50 V and 1000 V for alternating current and between 75 V and 1500 V for direct current).
- The low voltage directive also covers risks from external influences, e.g. mechanical or chemical. Germany transposed the LVD into national legislation through the Law on Product Safety (ProdSG) and its Ordinance on Electrical Devices (ProdSV).
- Electromagnetic compatibility. As with any electric appliance, a fridge creates radiation that may interfere with other electric equipment. It must therefore comply with the Electromagnetic Compatibility (EMC) Directive 2014/30/EU, which provides essential requirements. In line with these requirements, the fridge must be designed and manufactured so that electromagnetic emissions do not prevent other electrical equipment or devices from being operated as intended. Furthermore, the fridge must have a level of immunity to electromagnetic disturbance, enabling it to perform as intended without unacceptable degradation in the presence of an electromagnetic field. Germany transposed the EMC directive into national legislation through the Law on Electromagnetic Compatibility of Equipment (EMVG).

Health

- Restriction of hazardous substances. The EU restricts the use of hazardous substances (RoHS) in electrical and electronic equipment – such as cadmium or lead. This is stipulated in Directive 2011/65/EU. There used to be a separate label indicating RoHS compliance, but this is no longer necessary due to the CE marking. Germany transposed the RoHS directive into national legislation by passing the Material Ordinance for Electrical and Electronic Equipment (ElektroStoffV).
- Requirements for articles in contact with food. The refrigerator must comply with Regulation (EC) No 1935/2004, which mandates that any material or article
- intended to come into contact with food must preclude substances that can transfer to food in dangerous quantities. Uniform implementation of the regulation is supported through

Regulation (EC) No 2023/2006, which defines good manufacturing practices for materials intended for food contact. The label for compliant articles must include the text 'for food contact' or the symbol depicting a glass and fork.

- Noise: The EC Machinery Directive 2006/42/EC obliges the manufacturer or distributor of a machine to indicate the noise emission emitted by the machine in the operating instructions and sales brochures.

Environment

- Ecological requirements: The European Union's Eco-design Directive 2009/125/EC sets mandatory ecological requirements for products running most of their usage time in standby mode. Refrigerators in standby mode are allowed to consume only 0.5 W of power, in case of on-state power less than 50 W, even only 0.3 W. Only if additional functions like time or temperature are displayed, standby power might be up to 1 W.

- Recycling of electrical and electronic equipment. Most electrical and electronic appliances – including fridges – are made of complex materials and contain valuable resources that consumers should not consider household waste. The EU introduced Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) to increase the recycling of such appliances. Product users are alerted through symbols shown on the right. Germany transposed the WEEE directive by adopting the Law on Electrical and Electronic Equipment (ElektroG).

- Refrigerators and freezers with a fluorinated refrigerant GWP higher than 150 can no longer be placed on the market in the EU. Regulation (EU) No. 517/2014 on fluorinated greenhouse gases has been in force since 1 January 2015. The regulation aims to stop global warming through targeted measures. For household refrigerators and freezers used in private homes, a ban on the placing on the market of appliances with a GWP (global warming potential) of more than 150.

- Eco-design Requirements for Refrigeration Appliances Regulation (EU) 2019/2019 repeals and replaces Regulation (EC) No 643/2009.

Standardisation for refrigerators in Germany

DIN has adopted the most important international standards for refrigerators. Thus, a modified version of the test standard IEC 62552:2007 is called DIN EN 62552:2013-10 in Germany. This standard is also a harmonised European standard (EN), which is also used by regulatory authorities. Information on German standards can be found on the website of Publisher Beuth, which belongs to DIN[69].

3.3.2 Conformity assessment and accreditation

Key points in this section:

- **The EU is committed to the international recognition of conformity assessment results based on international accreditation.**
- **There is one government-authorised national accreditation body per EU Member State; these bodies are not allowed to compete or seek profit.**
- **EU delegates the responsibility for CA to the manufacturers.**
- **The CE mark indicates that the manufacturer has completed a conformity assessment procedure.**
- **Germany is a large market for voluntary conformity assessment.**

The private sector is responsible for conformity assessment

Following the New Approach, the European Union delegates the responsibility for CA to the manufacturers. CA generally takes place before a product is marketed. The system of government-authorised accreditation and notification of CABs by public authorities has proven to be effective in guaranteeing high-quality and trusted services by the private sector – even for high-risk areas such as chemical or medical equipment.

CE marking

Companies must provide a CE label if they want to sell their products on the European market. The acronym means "European Conformity" (in French Conformité Européenne) and proves that the product meets the requirements of the European Technical Regulation. It is also known as a "passport" to the European single market and applies to companies from the EU and third countries.

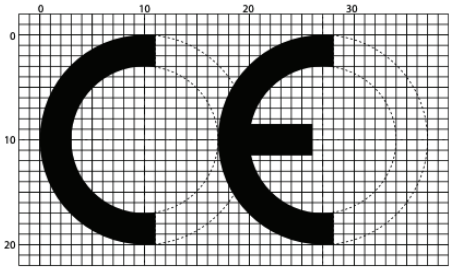

Figure 12: CE Mark
Source: European Commission.

CA for products regulated by EU harmonisation legislation

In some sectors, government bodies carry out CA themselves: the PTB, for example, carries out CA in the field of legal metrology (e. g., type examination of energy measuring instruments), and the BAM carries out CA in the field of technical safety, including containers for dangerous goods or explosive substances. Public bodies commonly carry out CA services in critical or legally defined sectors (e. g., homeland security or crime scene investigation), or in areas where public authorities have specific expertise because research and development are publicly funded (as in the case of BAM and PTB). Some assessments are not sufficiently economical to be offered by the private sector if investment in testing infrastructure is too great concerning the expected volume of tests.

In addition to the legally required CA for products, companies use voluntary quality marks. They use these to highlight special properties of the products or their manufacture to build up a competitive advantage. Examples are quality marks for products "Made in Germany" or for test procedures and specifications, e.g. for furniture, curtains or the Blue Angel (Blauer Engel) eco-label. Companies in a particular sector often join quality associations for this purpose.

Since 1925, a non-profit organisation, German Institute for Quality Assurance and Labelling (Deutsches Institut für Gütesicherung und Kennzeichnung e. V. - RAL), monitors the quality of the quality marks and awards the corresponding labels.[70]

Voluntary CA is of considerable significance to companies even if not mandated by law. In some cases, it could even become quasi-mandatory if, for example, business contracts between companies require the other party to be certified in line with relevant standards (e. g., management system certification based on ISO 9001). Companies also use certifications to signal to consumers that they comply with specific voluntary requirements (e. g. organic food certification).

Many organisations offer voluntary CA services. Any organisation can develop its own mark based on its defined criteria. Accreditation, therefore, provides a level of trust and helps distinguish credible marks from ones that are not trustworthy. So, although not mandatory for voluntary conformity assessment programmes, accreditation does add credibility. Under the German Accreditation Body Act, however, no person or organisation is permitted to issue a mark that gives the appearance of accreditation – this is reserved for DAkkS.

Many private CABs in Germany operate in regulated and non-regulated areas. These include the group of Technical Inspection Agencies (TÜV) or the German Motor Vehicle Inspection Association (DEKRA). The TÜV companies originated over 150 years ago from associations seeking to reduce the risks associated with pressure vessels. Today, their brand is so widely recognised throughout Germany and abroad that they are often incorrectly seen as public authorities – not least due to their testing and inspection work in regulated areas. However, they are private conformity assessment bodies.

Accreditation

In 2008, the EU created a uniform legal framework for accreditation by adopting Regulation (EC) No 765/2008. This framework reinforced accreditation to attest technical competence in regulated and non-regulated sectors for conformity assessment. It established the following principles:

- One accreditation body per country – EU Member States shall not set up more than one national accreditation body.
- Public authority activity – since accreditation is an activity in the public interest, public authorities are mandated to run an accreditation body themselves or task an organisation.
- Independence – accreditation bodies shall be independent of the conformity assessment bodies they assess.
- Trust – accreditation bodies shall ensure the competence, objectivity, impartiality and confidentiality of their activities; not-for-profit – accreditation bodies shall not seek profit or carry out their own conformity assessment or commercial consultancy services.
- No competition – accreditation bodies shall neither compete with other accreditation bodies nor with conformity assessment bodies.

Unifying a previously fragmented accreditation system: German Accreditation Body (DAkkS)

Until late 2009, the German accreditation system was fragmented: around 20 private and public accreditation bodies competed and had overlapping work areas. This changed when Germany implemented the requirements of Regulation (EC) 765/2008 through the German Accreditation Body Act. The law and its accompanying acts established the German Accreditation Body (Deutsche Akkreditierungsstelle GmbH - DAkkS) as the only accreditation body in Germany.

DAkkS is a non-profit organisation with the legal status of a limited liability company. Its shareholders are the Federal Republic of Germany (represented by the BMWK), the Federal states[71] and industry (represented by the Federation of German Industries (BDI). Each shareholder group holds a third of DAkkS shares. Although DAkkS is subject to government supervision, its accreditation decisions are made independently and impartially. DAkkS services are available to all CABs located in Germany.

[71] The shareholding Federal States are Bavaria, Hamburg and North-Rhine-Westphalia.

There are two ways in which DAkkS is financed. Most of its activities fall within the scope of its public authority in Germany and the European Economic Area. For such activities, accreditation fees are based on German national legislation regarding fees and duties. DAkkS is also permitted to operate outside its geographic scope and the area for which the government had primarily authorised it. For such activities, fees are based on the fee schedule prepared by DAkkS. For activities not directly related to accreditation or assessment activities – e. g. participation in committees – DAkkS receives funding from the Federal Government.

Data on conformity assessment

Table 3 shows the number of conformity assessment bodies accredited by the DAkkS in Germany. DAkkS is a signatory of IAF MLAs and ILAC MRAs for all accreditation scopes of-fered, except the new scheme for biobanking facilities ISO 20387:2018.

At 2431 (2021), the number of accredited testing laboratories has reached four digits. The number of accredited certification bodies for products (334) and management system certifications (448), calibration (504), medical laboratories (444), and inspection bodies (277) has reached three digits. The number of certification bodies for persons (50) and for validation and verification (24), as well as for proficiency testing (25) and reference material production (20), is in double figures.

Scope	Level 2	Level 3	MLA/MRA	Accredited CABs
IAF MLA	Product Certification	ISO/IEC 17065:2012	05/04/18	334
	Management System Certification	ISO/IEC 17021-1:2015	See footnote[72]	448
	Person Certification	ISO/IEC 17024:2012	20/10/16	50
	Validation and Verification	ISO/IEC 17029:2019	N.A.	24
	Greenhouse Gases	ISO 14065:2013	26/10/18	0
ILAC MRA	Testing	ISO/IEC 17025	02/11/00	2431
	Medical Laboratories	ISO 15189	02/11/00	444
	Calibration	ISO/IEC 17025	02/11/00	504
	Inspection	ISO/IEC 17020	24/10/12	277
	Proficiency Testing	ISO/IEC 17043	07/06/19	25
	Reference Material Production	ISO 17034	22/04/20	20
	Biobanking Facilities	ISO 20387:2018	N.A.	0

Table 3: Data on accredited CABs in Germany by DAkkS.
Source: Mesopartner/ GQII

[72] Food Safety ISO 22000:2018, 2005 (FSMS) 05.04.18, QMS ISO 9001:2015 (QMS) 22.01.98 Environmental ISO 14001:2015 (EMS) 09.10.2004, Information Security ISO/IEC 27001:2013 (ISMS) 05.04.18
Energy ISO 50001:2018, 2011 (EnMS) 05.04.2018, Medical Devices ISO 13485:2016 (MDMS) 05.04.18 and Occupational Health and Safety ISO 45001:2018 (previously OHSAS 18001) 05.02.2020.

Conformity assessment for refrigerators in Germany

Even if EU legislation does not mandate the involvement of a third-party conformity assessment body, refrigerator manufacturers may involve them voluntarily. These bodies support companies to increase their products' safety and quality and strengthen their market position. Voluntary testing and certification may refer to properties of the refrigerator, such as functioning, performance, sustainability and safety.

One example is the VDE Testing and Certification Institute (VDE Verband der Elektrotechnik Elektronik Informationstechnik - Association for Electrical, Electronic & Information Technologies.), which is active in the areas of Testing, Inspection and Certification (TIC). The VDE Institute is active in testing for safety, electromagnetic compatibility, inspections and the final certification. Corresponding DAkkS accreditations prove its independence and technical competence. The VDE mark for electrotechnical products like refrigerators indicates conformity with the VDE regulations or European or internationally harmonised standards. It confirms compliance with the protection requirements of the applicable directives. It also includes products within the meaning of the Product Safety Act (ProdSG).

The VDE mark for electrotechnical products like refrigerators indicates conformity with the VDE regulations or European or internationally harmonised standards. It confirms compliance with the protection requirements of the applicable directives. It also includes products within the meaning of the Product Safety Act (ProdSG).

The VDE mark represents the refrigerator's safety regarding electrical, mechanical, thermal, toxic, radiological and other hazards. It facilitates access to world markets for manufacturers of refrigerators due to the broad recognition of the certified test performance.

While it is up to the refrigerator manufacturer to contract any conformity assessment body, only accredited bodies will have passed an independent evaluation of their technical competence. Because of DAkkS' international agreements through IAF and ILAC, the choice of an accredited body has the advantage that its conformity assessment results are widely recognised internationally – thereby making it easier for manufacturers to access international markets. Here, the focus is not on any private quality mark since many such quality marks compete in a free market.

Figure 13: VDE Mark[73]

In the EU, accreditation is the preferred way of assessing the technical competence of any conformity assessment body that applies to become a notified body. Currently, ten notified bodies in Germany are approved for the EMC directive by the Bundesnetzagentur (BNetzA), the notifying authority responsible in Germany. During the evaluation process of a body seeking to become a notified body, the BNetzA checks whether it complies with the requirements set out in the EMC directive and with relevant standards.

As part of its assessment, the BNetzA also considers any accreditation certificates as per EN ISO/IEC 17025, if available. Even though accreditation is not mandatory, some notified bodies are accredited.

3.3.3 Metrology

Key points in this section:

- **Metrology in Germany and the EU supports international trade because it is embedded in the international metrology system.**
- **Germany takes part in peer reviews and mutual recognition arrangements on a regional and international level.**
- **Germany and the EU are drivers of continuous improvements in metrology and efforts to strengthen the international metrology network.**
- **Harmonised legislation on legal metrology – e. g., the accuracy of measurements and labelling of prepacked products – is a building block of the EU single market.**

Overview of metrology in Germany

The Physikalisch-Technische Bundesanstalt (PTB) is Germany's national metrology institute. PTB's role and responsibilities include realising and disseminating the international units of measurement, conducting research and development in metrology, and providing metrological services to industry and society. These responsibilities are defined in various laws, including the German Units and Time Act. As a higher scientific and technical federal authority and research institution, PTB comes under the jurisdiction of the German Federal Ministry for Economic Affairs and Climate Action (BMWK).

Based on its mandate, PTB provides a reliable and internationally recognised metrological infrastructure for the economy, science and research, and society. PTB's work is the basis for ensuring that consumers, businesses and public authorities can have confidence in the reliability and impartiality of measurements and tests.

PTB and DIs guarantee the chain of measurements

Measuring instruments are only accurate if they use the latest and most accurate measurement standards. On an international level, SI units are defined by the General Conference on Weights and Measures (CGPM) based on the Metre Convention. Together with three Designated Institutes (DI), PTB provides national measurement standards based on these international definitions. Three designated institutes support PTB:

- Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und -prüfung - BAM) in the field of chemical metrology;
- Federal Office for Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit - BVL) e. g. for residue measurements in food of animal origin;
- German Environment Agency (Umweltbundesamt - UBA) e. g. for measurements to do with air quality.

Accredited calibration laboratories and verification authorities use these national measurement standards to calibrate their working standards.

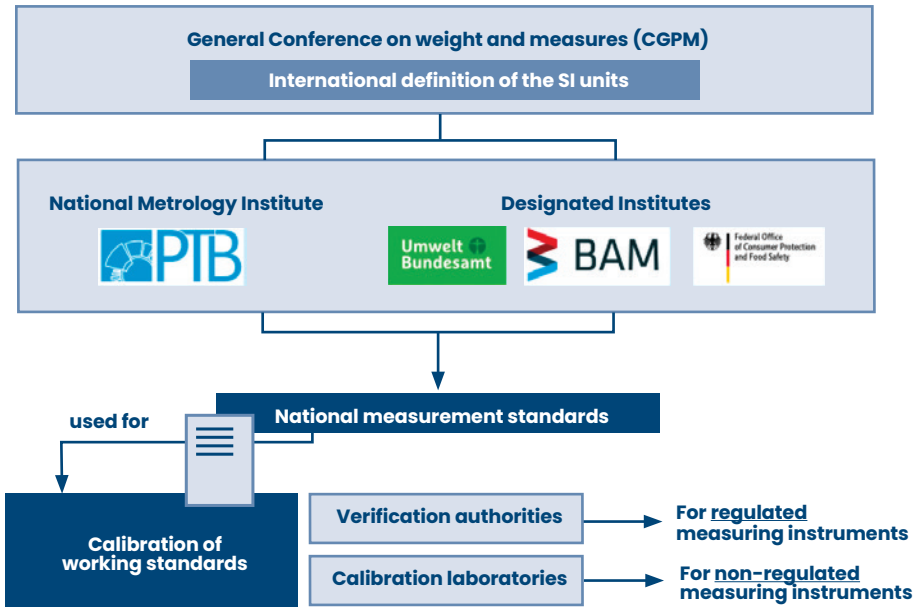

Figure 14: Chain of measurement standards in Germany. BMWK/ GPQI 2021, United in Quality and Safety.

Verification and calibration of measuring instruments

To ensure the accuracy of measuring instruments, the EU passed two directives that are in line with the provisions of the New Legislative Framework (NLF): Directive 2014/32/EU on measuring instruments (amended by Directive 2015/13/EU) and Directive 2014/31/EU on non-automatic weighing instruments. EU Member States then implemented these directives through national laws.

In Germany, the directives are enacted through the Measuring and Verification Law (Mess- und Eichgesetz, MessEG) and the Measuring and Verification Law (Mess- und Eichgesetz, MessEG). There is an EU-wide harmonised market for measuring instruments, which means they can move freely across EU borders. In addition, around 150 types of additional measuring instruments and devices are regulated at the national level.

The MessEG ensures that measuring instruments put into operation in Germany can be trusted throughout their lifetime. Consequently, measuring instruments for use in Germany with commercial or official transactions or measurements in the public interest must be conformity assessed by conformity assessment bodies and periodically reverified by verification authorities and officially recognised testing bodies. These verification authorities are established at the federal-state level. The MessEG makes users and manufacturers producing measuring instruments responsible for compliance. Like the CE marking, metrology uses an "M" mark for non-automatic weighing instruments,[74] and a voluntary 'E' mark (for estimated quantity) for pre-packaged goods.[75]

Reference materials are important benchmarks for measurements

Reference materials are essential to guarantee the accuracy and reliability of measurement results and generate confidence in analyses. In Germany, BAM provides the industry, research institutes, and authorities with high-quality reference materials targeted to their needs. At its online shop, BAM offers over 400 materials for different sectors, including iron and steel products, non-ferrous metals and alloys, for environmental and food purposes and polymers.

Leading role in metrology research and developments

Research and development are part of PTB's legal mandate and account for two-thirds of its activities. PTB is an active member of the European Association of National Metrology Institutes

[74] Directive 2014/31/EU and 2014/32/EU.
[75] Directive 76/211/EEC

(EURAMET) for non-legal metrology and the European Cooperation in Legal Metrology (WELMEC) for legal metrology. PTB carries out basic and applied research in collaboration with its many partners. Several of its research topics – improving the certainty of measurements, for example, or making quantities measurable – are of practical relevance to the industry.

PTB transfers newly developed metrological technologies to industry. PTB holds more than 150 patents and gives licenses to interested companies. Funded by Transfer of Metrological Technologies program (TransMeT), PTB supports SMEs in turning new metrological technologies into products.

Industrial metrology

PTB cooperates closely with the industry and around 400 accredited calibration laboratories. These laboratories are members of the German Calibration Service (DKD), a professional forum that works towards harmonising the calibration sector and supports the quality of calibration services in Germany.

International metrology cooperation

The German and European metrology systems are embedded in the international metrology system by the Metre Convention and OIML. As a result, they foster international recognition of national measurement standards and contribute to international harmonisation.

Metrology for refrigerators in Germany

In Germany, the PTB is responsible for the traceability of all relevant measurements to the International System. PTB is at the top of the national calibration pyramid. It ensures accurate measurements by accredited calibration laboratories, which calibrate refrigerator manufacturers' measuring instruments.

Department 7.4 is responsible for temperature measurement. Its Calibration and Measurement Capability (CMC) is confirmed through its participation in the International Commission on Weights and Measures (CIPM). The department is engaged in temperature metrology with contact sensors ranging from below 1 mK to above 2200 °C.

Fundamental questions like the new definition of the SI base unit kelvin and the support of more than 80 accredited calibration laboratories within the DAkkS. The accredited calibration laboratories ensure accurate measuring equipment for refrigerator manufacturers.

The accredited calibration laboratories ensure accurate measuring equipment for refrigerator manufacturers. This enables them to produce refrigerators so that their temperatures comply with the specified standards.

The Department 2.1 of PTB is responsible for measuring direct current and low frequency. It develops precision measuring instruments and calibrates the German Calibration Service (DKD) standards. In addition to obtaining precise results for electrical power, for the refrigerator to be declared safe, it must also be accurately measured for electrical conductivity. To do this, instruments measure the breakdown voltage of components in the refrigerator to determine at what voltage threshold insulators may become conductive – and therefore pose the risk of electric shock.

For the RoHS directive to work properly, chemical metrology is crucial. Only by measuring hazardous substances precisely can it detect levels dangerous to humans and the environment. Therefore, certified reference materials provided by BAM are crucial for accredited laboratories measuring the number of substances such as lead in refrigerators. The verification and calibration of measuring instruments is regulated by Directive 2014/32/EU.

3.3.4 Market surveillance

Market surveillance applies after a product is placed on the market. While the elaboration of the legal framework lies at the European level, Germany, as a Member State, is responsible for implementing market surveillance. The legal basis for market surveillance is set out in Regulation (EC) No 765/2008 and its amendments in Regulation (EU) 2019/1020.

Risk-based approach

Member States must provide all the necessary resources – e. g. financial, human and infrastructural – to stop non-compliant or unsafe products from becoming available on the market. Furthermore, they are required to establish a sanctions system per EU legislation. Authorities in Member States must monitor their market, create strategies to target risky products (e. g. by using statistics), take random samples and conduct planned tests, implement follow-up measures, and inform the public about their activities.

Authorities use a risk-based approach to identify what types of products to check, what kind of checks to implement and on what scale. Risk is determined by the potential hazard or other non-compliance associated with a product, a manufacturer's record of non-compliance, the extent to which a manufacturer can control activities and operations, and other information such as consumer complaints.

Safety Gate for dangerous non-food products

The Rapid Exchange of Information System (RAPEX) is the European Union's rapid alert system for unsafe consumer products and consumer protection.[76] RAPEX does not encompass food and pharmaceutical products and drugs. It does cover products such as clothing, shoes, cosmetics, jewellery, and toys with potentially harmful or low-quality ingredients or even products with technical faults, as well as electrical appliances that present an electric shock or ignition hazard.

RAPEX allows a quick exchange of information on measures such as repatriation or product recalls, whether carried out by national authorities or by voluntary action of manufacturers and distributors.

The EU has developed a general risk assessment methodology to assist market surveillance authorities when they assess a product's compliance with EU harmonisation legislation. The method builds on the RAPEX Guidelines,[77] which form part of the framework of the General Product Safety Directive.[78] It operates using criteria such as hazard groups, specific hazards arising from the product property, typical harm scenarios, and potential consequences. It then categorises each case in line with requirements.

Market surveillance process

Market surveillance authorities need to act and react promptly to be effective. They carry out planned activities, such as market surveillance campaigns for specific product groups (proactive market surveillance), and respond to outside events, including accident reports, consumer and competitor complaints and information from other authorities (reactive market surveillance). In both cases, the market surveillance process can be divided into five steps: (1) selection of products, (2) sample collection, (3) compliance assessment, (4) follow-up measures, and (5) informing the public.

Subsidiarity in market surveillance

In the European Union, the Member States are responsible for implementing market surveillance. In German federalism, this responsibility is implemented according to the principle of subsidiarity. This means that state tasks are only shifted to the next higher level if the lower level cannot adequately handle them. Figure 15 shows what the implementation of the principle of subsidiarity means for the distribution of competencies in product safety surveillance.

[76] The basis for establishing RAPEX is the General Product Safety Directive 2001/95/EC (GPSD), an EC Directive on general product safety, which came into force on 15 January 2004.
[77] Guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC, (05/12/22).
[78] See Directive 2001/95/EC, available at .

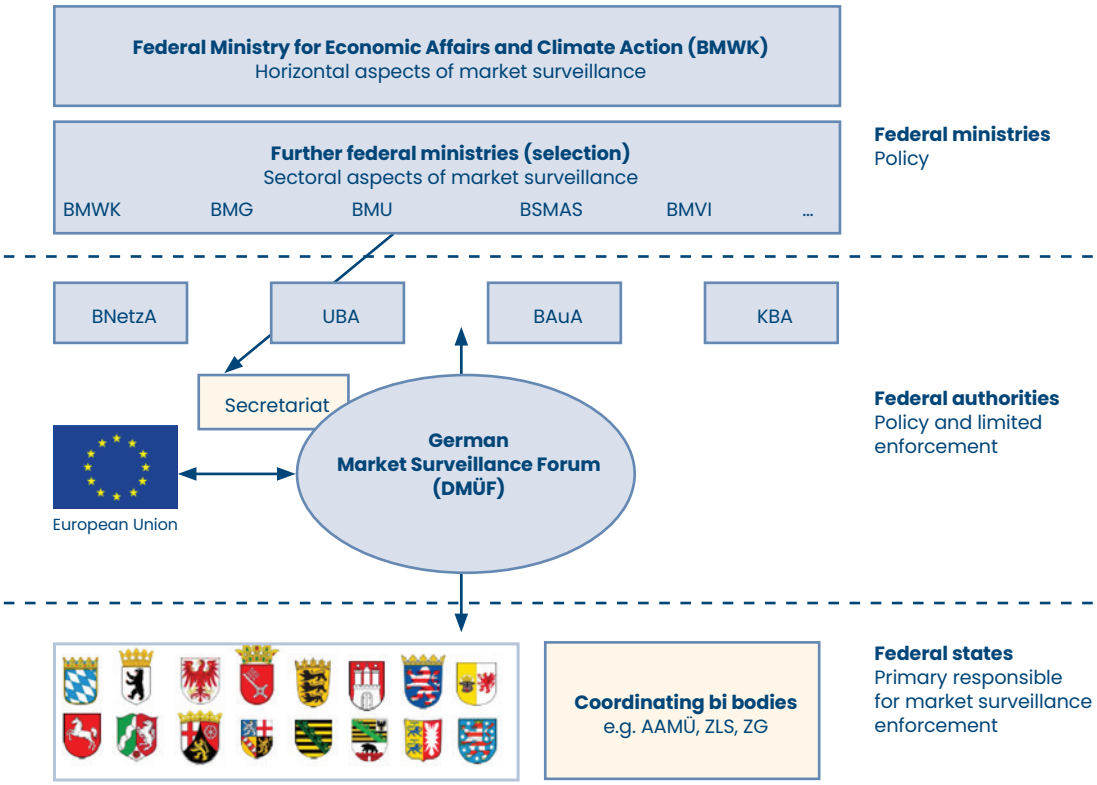

Figure 15: Overview of key institutions in the German market surveillance system.
Source: Own elaboration based on BMWI/ GPQI 2021, United in Quality and Safety.

In the first instance, the sixteen federal states are responsible for market surveillance for the various products. With the Working Committee on Market Surveillance (Arbeitsaussschuss für Marktüberwachung - AAMÜ), the Central Authority of the Federal States for Safety Technology (Zentralstelle der Länder für Sicherheitstechnik - ZLS) and the Central Authority of the Federal States for Health Protection of Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arneimitteln und Medizinprodukten - ZLG), federal states coordinate their market surveillance activities among themselves.

An important coordinating body is the German Market Surveillance Forum (Deutsche Marktüberwachungsforum, DMÜF). It is a body in which the responsible Federal Ministries and Länder agreed on a common interpretation of European law on market surveillance within the framework of Regulation (EC) No 765/2008 (and Regulation (EU) 1020/2019) and developed harmonised regulations for certain products such as machinery, radio equipment and toys. At the same time, the DMÜF serves as a platform for the exchange of information and consultancy. The DMÜF is part of the BMWK, and the Federal Network Agency (Bundesnetzagentur, BNetzA) oversees the secretariat.

Border controls and the role of customs authorities

Customs authorities play a crucial role in supporting market surveillance authorities by checking products during the import control process. National provisions on the role of customs vary across the EU: in some countries, customs authorities act as market surveillance authorities. In Germany, customs authorities are not market surveillance authorities.

Suppose customs authorities find a product which might present a risk or do not fulfil the formal requirements (e. g. incorrect CE marking or missing user manual in the German language). In that case, they suspend its release and notify the market surveillance authorities.

Market surveillance for refrigerators in Germany

BNetzA is responsible for monitoring the market for household appliances in Germany. The BNetzA checks household appliances in local shops and online sales platforms to see whether they comply with the Electromagnetic Compatibility of Equipment Act (EMVG) requirements and the Radio Equipment Act (FuAG).

In cooperation with customs, the BNetzA inspects products imported into the EU from third countries. In its own accredited measurement laboratory, it tests the products and determines hazards by measurement. Nationwide, the BNetzA tests the products according to the following criteria:

- Is the CE mark on the product present and correct?
- Can the product be identified and are the manufacturer's specifications correct?
- Is the product accompanied by German operating instructions, including the necessary instructions for use and warnings?
- Is a correct declaration of conformity available?

The results of BNetzA's work are compiled in a central place at the European Commission (ICSMS database).[79] You can use this database to report unsafe products, which the responsible market surveillance authorities can check. The market surveillance authorities of the federal states (Länder) are responsible, among other things, for checking energy labels on household appliances.

They regularly check whether the labels are clearly visible on refrigerators. The Länder also check on a random basis whether the appliances meet the performance characteristics stated on the labels. For this purpose, they use professionally competent test laboratories.

4. ANALYSIS AND COMPARISON BETWEEN THE SYSTEMS

Key points in this section:

- **Mexico can choose which elements it adopts for its QI from the US-American and European systems. The LIC shows references to both systems.**
- **Mexico promotes a culture of compliance, while "Made in Germany" is related to a culture of quality.**
- **Accreditation provides a reliable framework for internationally recognised, technically competent, and independent conformity assessment in both countries.**
- **Market surveillance in the European Union follows a risk-based approach. Mexico requires considerable effort to establish a similar system developing PLATIICA.**
- **Germany applies the subsidiarity principle to market surveillance, while Mexico follows a centralised approach.**

4.1 Similarities and differences between QI in Mexico and Germany

4.1.1 General aspects

Sense and approach of the comparison

This publication was produced in the context of the German Mexican Dialogue on Quality Infrastructure. Under the leadership of the BMWK and the Mexican Ministry of Economy, actors from the public and private sectors seek to learn from the experience of building and expanding a national quality infrastructure in order to adapt it to the new challenges of global trade in their respective countries.

The comparison of the two systems will first highlight the commonalities in aligning quality infrastructure with the international institutional framework of harmonising standards and the mutual recognition of conformity assessments. Furthermore, differences resulting from different national circumstances and needs will be highlighted. Finally, the aim is to emphasise "inspiring practices"[80] where Mexico can learn from Germany and Germany from Mexico when it comes to quality infrastructure.

Strengthening the EU single market for Integration in economic areas

Mexico and Germany are founding members of the WTO and members of the OECD and are jointly committed to free and rule-based international trade. Mexico is part of the North American Free Trade Area, while Germany is a member of the European Union and the European Single Market. Both countries have their largest trading partners in their respective regional markets.

The integration of the North American Free Trade Area is less deep than that of the European Single Market. Consequently, Mexico is governed by the national legal and regulatory framework, whereas the European Union legislation shapes the regulatory framework in Germany. As a result, Mexico must negotiate and coordinate the harmonisation of regulations and recognition of conformity assessment with its North American partners

[80] The concept of inspiring practices differs from good or best practices in that it considers national specificities and always foresees an adaptation of ideas to the other context.

under the USMCA agreement. It is also worth noting that Mexico has a greater degree of freedom to design its own QI system. The LIC is a good example of this.

Cultural differences between Europe and the United States of America

The references to the US and European QI systems are essential for understanding the Mexican QI system and its current reorientation. Again, both systems share the international reference framework of the WTO and the agreements on mutual recognition and harmonisation of international standards. However, the constitution of the standards and conformity assessment system differs fundamentally.

The European Union Member States usually have only one National Standardisation Body and one National Accreditation Body, which both the national governments and the European Union recognise. In contrast, the number of standardisation and accreditation organisations in the USA is large, and competition is explicitly encouraged. The US follows bottom-up standard development carried out by business associations, and, like the DGN in Mexico, the American National Standards Institute (ANSI) has a coordinating role.[81]

The US standards and accreditation organisations are increasingly active in Mexico, which the Ministry of Economy expressly sees as an enrichment of the system. Mexico can choose which elements it adopts for its QI from the US-American and European systems. The LIC shows references to both systems.

Culture of conformity and quality

QI systems always move within a national cultural framework that shapes their orientation and determines the possibilities for action. The term quality culture is used in the context of quality infrastructure. Experts see a national culture of quality, as well as the goal of a national quality policy.[82] Similar to the company level, this means that the principles of quality are supported and experienced by society. On the other hand, the Mexican Ministry of Economy names implementing a "culture of conformity" as the goal of the LIC, meaning the aim so for all companies to comply with the technical regulations (NOMs). While Mexican companies meet the technical requirements of leading economies on the export market, it is important to further strengthen the quality consciousness of consumers on the domestic market. Here, PROFECO plays an important role as an institution for consumer protection and market surveillance.

The idea of high-quality products is also associated with the designation of origin "Made in Germany".[83] Products made in Germany often have the reputation of being of high quality. Many relate German with engineering, inventiveness, state-of-the-art technical standards, and reliability. For this reason, consumers are willing to pay more for a product. For many manufacturers, using this label for their products is attractive.

However, the Made in Germany designation of origin is based solely on the manufacturer's self-declaration. The minimum criteria are that a significant part of the production and final assembly takes place in Germany and a decisive part of the value chain. There is neither a formal standard nor an independent conformity control.

Another component of the German quality culture is consumer protection. The Foundation for Consumer Protection (Stiftung Warentest) is a non-profit consumer organisation under civil law with legal autonomy.[84] Based on a state mandate, represented by BMWK, and funded with tax money, its employees investigate and compare goods and services from various providers and influence purchasing behaviour. Many consumers read their test reports. This creates incentives for manufacturers to improve the quality and performance of their products.

The dissemination of a quality culture is conducive to the functioning and impact of QI, and its promotion should also be the objective of the quality policy. The LIC, with the National Commission on Quality Infrastructure (CNIC), provides the institutional framework for such a policy. In Germany, on the other hand, there has yet to be a

[81] See American National Standards (ANS): Introduction.

formal and institutionalised quality policy. However, its beginnings can be seen in initiatives of the BMWK like QI-FoKuS Digital[85] which aims to improve understanding of the elements of QI and their interactions.

4.1.2 Technical Regulation and Standardisation

As members of the WTO, Mexico and Germany distinguish between mandatory technical regulations and market-driven standards.

In Mexico, NOMs are at the system's centre, and different ministries and state institutions are responsible for their elaboration and implementation. In Germany, the European Union sets the framework of technical regulations, and the member states are responsible for their implementation.

Mexico's standardisation follows the US model with various private standards. As standards development bodies, national business organisations develop sectoral standards. In addition, the LIC also allows the involvement of foreign standard bodies in Mexico, which US standard bodies (e.g., ASTM International and UL) are beginning to exercise.

A major difference between the U.S. and Mexico is that the DGN is a government agency responsible for coordinating voluntary standards and technical regulations. In contrast, ANSI is a private, non-profit organisation coordinating U.S. voluntary standards. With DIN and DKE, the German national standard bodies are also private non-profit institutions.

In Germany, DIN and DKE are private-law institutions recognised as national standards bodies through a cooperation agreement with the state. DIN has also introduced an alternative fast track in standardisation (SPECS), which supports technological development.

4.1.3 Conformity assessment and accreditation

In both countries, there is a wide range of CABs in laboratories, inspection bodies, and management certification bodies. The supply of CABs in Mexico is particularly concentrated in Mexico City and on the border with the USA. In Germany, conformity assessment bodies are distributed throughout the country, where the federal system imposes specific requirements in federal states. Companies in Germany are obliged to carry out CA themselves. They demonstrate the conformity of their products with the CE mark. With the implementation of the LIC, the responsibility of self-declarations lying with Mexican companies could expand, which could relieve the state surveillance authorities.

Accreditation provides a reliable framework for internationally recognised, technically competent and independent conformity assessment. The accreditation bodies in both countries offer accreditation in almost all internationally available accreditation schemes. ema in Mexico is on its way to obtaining international accreditations for personal certification systems ISO/IEC 17024:2012, and MAAC and SIAAC are working on the expansion and international recognition of their services. On the other hand, DAkkS and ema are evaluating the option of expanding their offer of accreditation for biobanking facilities ISO 20387:2018.

Regarding the number of accreditation bodies, Mexico and Germany are moving in opposite directions. While Germany has implemented the requirements of the EU and merged the ten accreditation bodies into one national accreditation body (DAkkS), there are now three national accreditation bodies in Mexico, following the approval of MAAC and SIAAC. Therefore, Mexico is now following the US-American model in accreditation.

4.1.4 Metrology

With the signing of the Metre Convention, Germany and Mexico (1875 and 1890, respectively) were among the pioneers of international metrology and the international system (IS) of measurements. While in Germany, the National Metrology Institute (PTR/PTB) was established and expanded in close cooperation between the state, industry and science, Mexico had a National Metrology Institute for the first time in 1994 with the foundation of CENAM. In less than three decades it has developed into one of the most respected metrology institutes in the Americas, and even the world.

PTB is responsible for all three scientific, legal and industrial metrology areas. Up to now, CENAM has been primarily responsible for industrial and scientific metrology. With the LIC, CENAM has also formally taken over the competencies in legal metrology.

While the network of accredited calibration laboratories in Germany has been expanded, in Mexico there is still considerable potential for development in this respect.

4.1.5 Market surveillance

With the new law, the Mexican government aims to enforce a culture of compliance in the domestic market. The reform of market surveillance is based on the European model with its risk-based approach. The development of the PLATIICA information platform will play an important role in this. The European RAPEX system can serve as an inspiration here. In accordance with the subsidiarity principle, the federal states in Germany play a central role in the implementation of market surveillance. In Mexico, on the other hand, the market surveillance system is anchored at the central level of the Federation.

Features	Mexico	Germany
Institutional and legal framework	The aspiration is a culture of compliance LIC provides a systemic legal framework	"Made in Germany" is related to a culture of quality In Germany there is no overarching legal framework
Technical regulations	NOMs are the central instrument of the regulatory system and can be quite specific.	EU harmonisation legislation mandates essential requirements for the protection of public interest.
Standardisation	DGN follows the US-model with various private standardisation bodies.	DIN and DKE are private-law institutions recognised as national standards bodies through a cooperation agreement with the state. DIN-SPEC open a fast track for new technologies.
Accreditation	Several national accreditation bodies (ema, MAAC and SIAAC). Competition is desirable for the quality of accreditation.	One national accreditation body (DAkkS). The quality of accreditation is ensured by the operation of a single entity.
Conformity assessment	Conformity assessment is mainly used for the export market, whereas domestic companies hardly use conformity assessment.	Conformity assessment is the passport for companies to the single European market.
Metrology	CENAM started with trade liberalisation Supports industrial measurement and legal metrology (new).	PTR/PTB started by a public-private initiative Strong focus on scientific research and legal metrology.
Market surveillance	Centralised approach.	Subsidiarity principle to market surveillance Risk-based approach.

Table 4: Special features of the QI systems in Mexico and Germany. Source: Own elaboration

4.1.6 "Inspiring Practices"

With the signing of the Metre Convention, Germany and Mexico (1875 and 1890, respectively) were among the pioneers of international metrology and the international system (IS) of measurements. While in Germany, the National Metrology Institute (PTR/PTB) was established and expanded in close cooperation between the state, industry and science, Mexico had a National Metrology Institute for the first time in 1994 with the foundation of CENAM. In less than three decades it has developed into one of the most respected metrology institutes in the Americas, and even the world.

PTB is responsible for all three scientific, legal and industrial metrology areas. Up to now, CENAM has been primarily responsible for industrial and scientific metrology. With the LIC, CENAM has also formally taken over the competencies in legal metrology.

Bearing in mind the cultural and institutional differences between the Mexican and German QI, identifying the "inspiring practices" in both systems offers opportunities for mutual learning and new potential areas of cooperation. In the case of Mexico, the efforts to promote gender equality in QI, the systemic legal framework offered by the Law on Quality Infrastructure and the coherence achieved by integrating committees and platforms like the National Commission for Quality Infrastructure and the digital integrating platform "PLATIICA" stand out.

On the other hand, in the case of Germany and the European Union, the subsidiarity and coordination mechanisms in market surveillance offer valuable lessons, as well as the innovation-friendly New Legal Framework governing product legislation in the EU.

Mexico offers valuable experiences in **integrating SDG 5 Gender Equality in the QI system**. In particular, the women's civil association MUSICA (MUjeres del SIstema de Infraestructura de la CAlidad), officially founded in 2023[86], promotes the integration of a gender perspective in Metrology, Standardisation, Conformity Assessment, Quality and Accreditation. Among other activities, MUSICA develops and promotes standards on gender equality at the workplace and offers capacity building and mentoring opportunities for women in QI. It provides a rich learning experience for efforts to establish networks between women in QI, monitor and evaluate the representation of women in different QI institutions, and pave the way for strengthening women's participation in QI-related activities.

In a different vein, with the 2020 **Quality Infrastructure Law** (Ley de Infraestructura de la Calidad) replacing the Federal Law on Metrology and Standardisation (LFMN), a systemic legal framework for QI was created in Mexico that regulates QI and defines the division of labour between the different QI bodies. The law stipulates the creation of committees and platforms that integrate QI actors and processes, thereby increasing the coherence, transparency and efficiency of the national QI system.

The **National Commission for Quality Infrastructure** is the national body responsible for annually reviewing, analysing and approving the National Quality Infrastructure Programme and its Supplement, monitoring its compliance, and responsible for directing and coordinating activities in the fields of standardisation, conformity assessment and metrology.

It is chaired by the Mexican Ministry of Economy and integrates the subdivisions concerned with QI in each ministry, sectoral regulation bodies and business associations, ensuring the representation of the relevant stakeholders in the design of QI activities, and facilitating the exchange between the different QI institutions in Mexico.

PLATIICA, on the other hand, is a new digital platform where data, processes, procedures, services, technical regulations, standardisation, conformity assessment and metrology activities will be managed and executed in a systematised way.

It will be the main means of dissemination and consultation of mandatory NOMs, standards and national measurement standards, increasing the accessibility of Mexican standards and technical regulations.

In the case of the German QI system, which is deeply embedded in the European Common Market, the **German Forum for Market Surveillance** (Deutsches Marktüberwachungsforum, DMÜF) offers good practice in the effective coordination between the market surveillance authorities. In uniting market surveillance authorities, technical experts as well as representatives of the highest federal and state authorities, the German Accreditation Body GmbH (DAkkS) and the customs administration in one commission, it facilitates an efficient exchange of information, best practices and identification of common challenges.

On the other hand, the principle of **subsidiarity applied to market surveillance activities** in Germany, lying within the responsibilities of the 16 federal German states, makes it possible to tailor market surveillance strategies to the characteristics and sectoral structure of each state. By making use of location-specific knowledge and case-specific targeting of economic activities, both efficacy and efficiency of market surveillance activities can be increased.

Finally, on the European Level, the **New Legislative Framework (NLF)** governing a major part of German product legislation offers significant benefits to both public and private sector actors while ensuring effective product safety and quality. By restricting mandatory product regulation to essential requirements, and leaving technical specifications to voluntary harmonised standards, it allows for quick adaptation to new trends and technological innovations.

In refraining from specifying technical details in product regulation, the NLF also stimulates innovation in firms as they come up with new processes and technologies to meet the essential requirements. The clear separation between mandatory and voluntary work further unburdens authorities from the task of continuously updating detailed technical regulations, and can help liberate human and time resources in the face of tight public budgets.

These "inspiring practices" and elements of the Mexican and German QI systems can point towards new channels for mutual learning, and potential areas of collaboration between QI institutions in both countries.

5. OPPORTUNITIES AND CHALLENGES FOR QI IN MEXICO AND GERMANY

Key points in this section:

- **QI needs to respond to new digital technologies and global environmental threats.**
- **QI supports digital transformation and must digitalise itself.**
- **Circular economy requires measurements, standards, and conformity assessment.**

Given the dynamic development of new digital technologies and global environmental threats, the challenge for QI is to continue to evolve.

QI for digitalisation and digitalisation of QI

Digitalisation is continuously generating new products and services. This presents a challenge for current QI systems developed against the background of more linear product development, production and distribution processes.

Today's products combine hardware and software and change dynamically once they have arrived on the market: software updates, for example, may add new functions that affect a product's safety. Challenges also arise from the arrival of additive manufacturing, also known as 3D printing, which enables new production methods for custom-made products – i.e. those that can be manufactured at a batch size of one. Here, type approval or destructive test procedures would not be feasible.

Eventually, the need for international standards and specifications for key technologies like Artificial Intelligence (AI) will also generate the requirement of adjustments and new developments in a digitalised QI, starting with the identification of existing standards and specifications for AI suitability and ultimately the realisation and use of smart standards, as this was also carved out in the German Standardisation Roadmap on Artificial Intelligence[86] jointly published by DIN, DKE and BMWK. So new approaches are required to ensure the quality and safety of products.

German experts are actively working on such challenges and aiming to make QI fit for the digital age. One initiative is the "QI Digital" consortium, jointly founded by BAM, DAkkS, DIN, DKE and PTB and supported by BMWK. The goal is to develop a vision of QI in the digital age – to address the challenges of digitalisation and exploit its potential. Germany emphasises that this is not a task that can be done at national level. For this reason, the results of this initiative will be used in cooperation with Germany's international partners.

The mission of QI Digital consortium is to investigate use cases to analyse the practical implications of emerging technologies on quality infrastructure:

- New products and production technologies: use case on additive manufacturing. Additive manufacturing – 3D printing – is of growing relevance in many sectors, including aerospace, energy and medical technology. The advantages of the technology include short production chains, the economy of short production runs ("batch size of one"), and the variety of shapes and complexity of components it can achieve. Conventional CA methods are often not adequate in this case. The initiative therefore aims to develop new procedures for process-integrated quality assurance, non-destructive testing methods, and exploration of the use of new digital methods to evaluate process and measurement data. There are also plans to create a database for reference data on additive materials and to develop certification guidelines.
- Digital processes for quality infrastructure: use case on hydrogen filling stations. If hydrogen is to develop its potential as a future energy source, a network of safe filling stations is needed. This in turn requires a reliable digital network that uses data from various sensors, uses digital twins and deals with interfaces between actors such as producers, suppliers and customers. The digital hydrogen

infrastructure is, therefore, a complex challenge for quality assessment: Are data accurate, traceable, and impossible to manipulate, for example? For this reason, QI Digital seeks to analyse how modern QI can build trust within such a digital system. This includes using digital calibration certificates for filling stations, distributed ledger systems – or blockchain – to verify information, and smart standards that machines can read automatically.

Metrology for Digital Transformation

In Mexico, CENAM participates in the regional project "M4DT (Metrology for Digital Transformation)" within the framework of the Interamerican Metrology System (Sistema Inter-americano de Metrología - SIM). With the support of PTB, CENAM exchanges information with other NMIs in the region about the possibilities of digital transformation and organises a knowledge exchange. The aim is to use digital tools to define the direction of digital transformation for NMIs.

This involves the contribution of NMIs to digital transformation and the digital transformation of NIMs. Metrology in digital transformation has implications for a wide range of topics: Laboratory Process Automation, Digitalisation in Legal Metrology, Digital Calibration Certificate, Metrology for Industry 4.0, and Digital Transformation Strategy for NMIs.

As part of the project, CENAM aims to increase knowledge about the trends with the most significant impact on digital transformation. Specific topics include Metrology 4.0, Metrological Cloud, digital certificates, metrological traceability of items, digital twins, and cybersecurity.

QI for the circular economy

Faced with the challenge of climate change, humanity fundamentally transforms how it does business and consumes. The transformation to a green economy also challenges quality infrastructure in Mexico and Germany to effectively support this development with measurement techniques, standards, and CA.

One field of action is the transition from a linear to a circular economy. The Mexican QI institutions are participating in a regional project of German development cooperation with the Organization of American States (OAS) of the Quality Infrastructure Council of the Americas (QICA) on quality infrastructure for the circular economy (QI4CE).[87]

This project aims to identify the QI needs of companies in the developing circular economy and to implement them in individual value-added cycles (agrifood, construction and plastics). In this context, CENAM is developing procedures, for example, to determine whether the packaging is biodegradable. This service is essential for certification bodies and public and private procurement.

Circular Economy Standardisation roadmap

In Germany, DIN, DKE and VDI are working on standardising the circular economy. The standardisation roadmap aims to provide an overview of the status quo of standardisation in the field of circular economy, to describe requirements and challenges for seven key topics and to identify and formulate concrete needs for action for future standards.

The circular economy is of particular importance in achieving the goals of the European Green Deal[88] and the Climate Protection Act[89]. New and revised technical regulations for the circular economy are needed to achieve the ambitious climate protection goals. The Circular Economy Standardisation Roadmap sets the path for this and thus drives forward the green transformation of Germany and Europe.

It sets seven focus topics: electrical engineering & ICT, batteries, packaging, plastics, textiles, buildings and municipalities, and digitalisation/ business models/management. These topics are based on the focus topics of the Circular Economy Action Plan of the EU.

Representatives from business, science, the public sector and civil society will draw up the roadmap's contents. Experts from the Circular Economy will contribute their ideas. Since January 2022, the Standardisation roadmap has been developed in seven working groups - corresponding to

the seven main topics of the Circular Economy Action Plan.

The Circular Economy Advisory Board of DIN and DKE in the Environmental Protection Coordination Office (KU) coordinates the work on the Standardisation roadmap. It includes leading figures and experts from business associations, civil society organisations, science and research institutions and the public sector. The Federal Ministry for the Environment and Nuclear Safety (BMUR) and the Federal Environment Agency (BAU) support this initiative.

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7. FURTHER READINGS

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