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GPQI

United in Quality and Safety

An introduction to quality infrastructure in Germany and the European Union for policymakers and trade partners

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About this publication

United in quality and safety – throughout Europe and beyond

A shared understanding of the quality and safety of products establishes trust. The EU single market demonstrates how trust has helped create an economic area in which products can move freely across borders – while setting high targets to protect people's health, safety, the environment and climate as well as consumers' rights. Quality and safety play a critical role in bringing people and markets together. The growing interdependence of markets resulting from international value chains and digitalisation calls for greater international understanding on matters of quality and safety.

Germany's international cooperation on quality infrastructure

For this reason, the Federal Ministry for Economic Affairs and Energy (BMWi) engages in policy and expert dialogues with major partners on quality infrastructure – the system and processes relating to standardisation, conformity assessment, accreditation, metrology and market surveillance. These dialogues with partner countries, including Brazil, China, India, Indonesia and Mexico, take place within the ministry's Global Project Quality Infrastructure (GPQI). In addition, there is a cooperation with Canada, the Eurasian Economic Union (EAEU) and the United States. By bringing together all relevant stakeholders, GPQI works towards reducing technical barriers to trade, enhancing product safety and strengthening consumer protection.

A publication on quality infrastructure in Germany and the EU

This publication is for all who seek a better understanding of the approach to placing products on the market in the EU and Germany with the shared responsibilities of regional harmonised product legislation and quality infrastructure mechanisms and are keen to learn how the different elements of quality infrastructure contribute to achieving high-quality, compliant products and services. More specifically, this publication is written for public officials, policymakers and experts in countries which trade – or wish to deepen economic ties – with Germany and the EU. We also invite experts from industry associations and companies, research and academia, and anyone in the general public with an interest to read this publication.

A joint effort of German quality infrastructure institutions

This publication was developed under the framework of GPQI of the Federal Ministry for Economic Affairs and Energy. It is the result of a collaboration between the key quality infrastructure institutions in Germany: the Federal Institute for Materials Research and Testing (BAM), the Bundesnetzagentur (Federal Network Agency, BNetzA), Germany's National Accreditation Body (DAkkS), the German Institute for Standardization (DIN), the German Commission for Electrical, Electronic & Information Technologies of DIN and VDE (DKE), the National Metrology Institute of Germany (PTB) and the Central Authority of the German Federal States for Safety Technology (ZLS). The publication was coordinated and edited by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH under the framework of GPQI.

Content

List of abbreviations

AAMÜ	*Arbeitsausschuss Marktüberwachung* Working Committee on Market Surveillance
ACER	Agency for the Cooperation of Energy Regulators
AdCo(s)	Administrative Cooperation Group(s)
AI	Artificial intelligence
AkkStelleG	*Gesetz über die Akkreditierungsstelle (Akkreditierungsstellengesetz)* Accreditation Body Act
APAC	Asia Pacific Accreditation Cooperation Incorporated
BAF	*Bundesaufsichtsamt für Flugsicherung* Federal Supervisory Authority for Air Navigation Services
BAG	*Bundesamt für Güterverkehr* Federal Office for Goods Transport
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
BDI	*Bundesverband der Deutschen Industrie* Federation of German Industries
BIPM	*Bureau International des Poids et Mesures* International Bureau of Weights and Measures
BLAC	*Bund/Länder Arbeitsgemeinschaft Chemikaliensicherheit* Working Committee of the Federal Government and the Federal States on Chemical Safety
BLE	*Bundesanstalt für Landwirtschaft und Ernährung* Federal Office for Agriculture and Food
BMAS	*Bundesministerium für Arbeit und Soziales* Federal Ministry of Labour and Social Affairs
BMG	*Bundesministerium der Gesundheit* Federal Ministry of Health

BMI	*Bundesministerium des Innern, für Bau und Heimat* Federal Ministry of the Interior, Building and Community
BMU	*Bundesministerium für Umwelt, Naturschutz und nukleare Sicherheit* Federal Ministry for the Environment, Nature Conservation and Nuclear Safety
BMVI	*Bundesministerium für Verkehr und Digitale Infrastruktur* Federal Ministry of Transport and Digital Infrastructure
BMWi	*Bundesministerium für Wirtschaft und Energie* Federal Ministry for Economic Affairs and Energy
BMZ	*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung* Federal Ministry of Economic Cooperation and Development
BNetzA	*Bundesnetzagentur* Federal Network Agency for Electricity, Gas, Telecommunications Post and Railway
BVL	*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* Federal Office of Consumer Protection and Food Safety
CE	Communauté/Conformité Européenne (European Community/Conformity)
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CETA	Comprehensive Economic and Trade Agreement
CIPM	International Committee for Weights and Measures
DAkkS	*Deutsche Akkreditierungsstelle* Germany's national accreditation body
DEKRA	*Deutscher Kraftfahrzeug-Überwachungs-Verein* German Motor Vehicle Inspection Association
DFG	*Deutsche Forschungsgemeinschaft* German Research Foundation
DIBt	*Deutsches Institut für Bautechnik* German Institute for Construction Engineering

DIHK	*Deutscher Industrie- und Handelskammertag* German Chambers of Industry and Commerce
DIN	*Deutsches Institut für Normung* Association of German Institute for Standardization
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 VDE
DMÜF	*Deutsches Marktüberwachungsforum* German Market Surveillance Forum
EA	European co-operation for Accreditation
EAEU	Eurasian Economic Union
EBA	*Eisenbahn-Bundesamt* Federal Railway Authority
EFTA	European Free Trade Association
EMC	Electromagnetic compatibility
EMPIR	European Metrology Programme for Innovation and Research
ETSI	European Telecommunications Standards Institute
EU	European Union
EURAMET	European Association of National Metrology Institutes
FTA	Free trade agreement
GDP	Gross domestic product
GIZ	*Deutsche Gesellschaft für Internationale Zusammenarbeit*
GPQI	Global Project Quality Infrastructure
GPSD	General Product Safety Directive

GS	*Geprüfte Sicherheit* "Tested Safety" (mark)
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
ICSMS	Information and Communication System on Market Surveillance
IEA	International Energy Agency
IEC	International Electrotechnical Commission
IECEE CB	IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components Certification Body
ILAC	International Laboratory Accreditation Cooperation
IRG	Independent Regulators Group
ISO	International Organization for Standardisation
ITU	International Telecommunication Union
KBA	*Kraftfahrt-Bundesamt* Federal Motor Transport Authority
LBA	*Luftfahrt Bundesamt* Federal Aviation Office
MLA	Multilateral recognition agreement/multilateral agreement
MRA	Mutual recognition agreement/arrangement
MessEG	*Mess- und Eichgesetz* Measures and Verification Act
NAM	*DIN-Normenausschuss Maschinenbau* DIN Standards Committee Mechanical Engineering
NANDO	New Approach Notified and Designated Organisations
NoBoMet	European Platform of Notified Bodies working in Legal Metrology

NLF	New legislative framework
OIML	International Organization of Legal Metrology
OIML-CS	OIML certification system
OJEU	Official Journal of the EU
PPE	Personal protective equipment
PTB	*Physikalisch-Technische Bundesanstalt* National Metrology Institute of Germany
ProdHaftG	*Produkthaftungsgesetz* German Product Liability Act
ProdSG	*Produktsicherheitsgesetz* German Product Safety Act
PROSAFE	Product Safety Forum of Europe
QI	Quality infrastructure
RAPEX	EU rapid alert system for dangerous non-food products (Rapid Exchange of Information System)
RED	Radio Equipment Directive
SDO(s)	Standards developing organisation(s)
SI	International System of Units
StMUV	*Bayerisches Staatsministerium für Umwelt und Verbraucherschutz* Bavarian State Ministry of the Environment and Consumer Protection
TBT	Technical barrier to trade
TEU	Treaty on European Union
TransMeT	Transfer of Metrological Technologies of BMWi
TFEU	Treaty on the Functioning of the European Union
TRIS	Technical Regulations Information System database

TÜV	*Technischer Überwachungsverein* Technical inspection association
UBA	*Umweltbundesamt* German Environment Agency
UNECE	United Nations Economic Commission for Europe
VDA	*Verband der Automobilindustrie* Federal Association of the Automotive Industry
VDE	*Verband der Elektrotechnik Elektronik Informationstechnik* Association for Electrical, Electronic & Information Technologies
VDMA	*Verband Deutscher Maschinen- und Anlagenbau* German Mechanical Engineering Industry Association
WELMEC	European Cooperation in Legal Metrology (earlier: Western European Legal Metrology Cooperation)
WTO	World Trade Organization
ZDH	*Zentralverband des Deutschen Handwerks* German Confederation of Skilled Crafts
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
ZLS	*Zentralstelle der Länder für Sicherheitstechnik* Central Authority of the Federal States for Safety Engineering

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Executive summary

Quality infrastructure ensuring quality and safety that surrounds us every day

Quality infrastructure is a system that covers everything needed to ensure safe, high-quality products and services: from standardisation, conformity assessment (testing, inspection and certification) and accreditation to metrology and market surveillance. These elements form the system and processes that protect people, health and the environment. Quality infrastructure plays a vital role for business, innovation and trade – both nationally and across borders.

Quality and safety without borders: the importance of international cooperation

Global trade, cross-border value chains and international online commerce call for a global outlook. Product quality and safety do not stop at the borders of national states. International trade is easier if the legal and technical requirements that companies have to fulfil do not differ from country to country. Standards developed at the international level create a common language. They are invested with the knowledge and broad acceptance of experts around the world and preclude the need to duplicate work. Internationally recognised accreditation increases trust in conformity assessment and renders repeated testing unnecessary. In short: The system of quality infrastructure is effective when harmonised internationally.

Germany supports the international harmonisation of quality infrastructures

To support the international harmonisation of quality infrastructures, the Federal Ministry for Economic Affairs and Energy (*Bundesministerium für Wirtschaft und Energie*, BMWi) cooperates with international partner countries. Germany consolidated and amplified these efforts in 2017 with the establishment of the Global Project Quality Infrastructure (GPQI). GPQI enables Germany to engage in international cooperation on quality infrastructure with major trading partners. With countries such as Brazil, China, Mexico, India and Indonesia, the project is implemented with the support of the *Deutsche Gesellschaft für Internationale Zusammenarbeit* (GIZ) GmbH. With other partners, including Canada, the Eurasian Economic Union (EAEU), and the United States, the project is implemented in cooperation with other partners including the German Chambers of Commerce (AHKs). The project's political and technical dialogues bring together experts from public and private sectors, standardisation and accreditation bodies, metrology institutes and technical-scientific institutions. All involved are focused on working to reduce technical barriers to trade, strengthening product safety and enhancing consumer protection.

Product legislation in the EU: a business-friendly approach that protects public interests

Home to over 450 million people, the European Union (EU) today forms one of the largest economic areas in the world: the EU single market. This market is known for regulation that emphasises the protection of workers, consumers, climate and the environment. Yet despite stringent legal requirements, the single market remains attractive to businesses both inside and outside the EU. The EU has developed a system for the placing of products on the market that grants manufacturers a substantial degree of freedom but holds them accountable through effective public oversight. To strike this balance, the system builds on the strengths of each element of quality infrastructure. This approach has helped remove barriers to trade in Europe and

establish the single market. What is more, it has been shown to stimulate innovation and support a modern and internationalised economy.

Key aspects of the EU's legislative approach to the single market for goods

Goods circulate freely on the single market. The EU created its single market through a combination of product legislation harmonised across the EU and mutual recognition of national requirements. If a sector is not covered by EU harmonisation legislation, national rules of Member States may apply.[1] However, the free movement of goods is ensured in non-harmonised sectors, because any product that is lawfully sold in one Member State can be made available in another.

Most EU harmonisation legislation is limited to essential requirements. Most EU harmonisation legislation only mandates compliance with essential requirements for the protection of public interests. It does not prescribe the detailed technical solutions that manufacturers must follow. This unburdens legislators and creates a stable regulatory environment because regulators are not obliged to update product legislation beyond essential requirements in lengthy legislation processes.

Voluntary standards support product legislation. Technical details are left to voluntary standards, which manufacturers may use to demonstrate compliance. But manufacturers may also use other technical specifications to fulfil the essential requirements – an approach which of itself promotes innovation in the private sector. Nevertheless, besides the advantages of cost and time savings to using standards, there is one particular advantage especially when using so-called harmonised European standards – i.e. those developed by the European standardisation organisations upon request from the European Commission in order to support EU legislation. When manufacturers use these harmonised European standards published in the Official Journal of the EU, they benefit from a presumption of conformity. And it means that market surveillance authorities are then required to proof that a product does not comply with essential requirements – reversing the burden of proof.

Broad responsibilities for the manufacturer. The manufacturer is responsible for performing an initial risk assessment and demonstrating compliance with essential requirements through conformity assessment. By affixing the CE marking and issuing an EU declaration of conformity, manufacturers declare that a product covered by EU harmonisation legislation meets all legal requirements for CE marking and can be sold throughout the European Economic Area. The CE marking is not a quality indicator or a certification mark and serves primarily as a 'passport' for goods to move freely on the single market.

A range of conformity assessment modules fit varying requirements. EU legislators may choose from a set of conformity assessment modules. Their choice depends on the degree of risk associated with the product. Many products require only the manufacturer's declaration of conformity, with no involvement of a third-party conformity assessment body. Others require the involvement of an accredited in-house conformity assessment body that forms an independent part of the manufacturer's organisation. For some products, involvement of a third-party conformity assessment body is mandatory. Such third-party bodies are called notified bodies,

1 This publication uses the term "legislation" instead of the global term (technical) "regulation" to allow for a differentiation between different types of EU legislation (e.g. EU regulations and EU directives).

since they are authorised by their Member States and notified to the EU.

Government-authorised accreditation bodies establish trust in conformity assessment. The EU has established a uniform framework that reinforces accreditation as a means of attesting technical competence for conformity assessment in both regulated and non-regulated sectors. There is one national accreditation body per EU Member State; conformity assessment bodies can only seek accreditation from the accreditation body within their territory. To avoid race-to-the-bottom competition and establish trust in accreditation, these bodies are not allowed to compete or seek profit. Peer evaluation at the European level builds confidence among national accreditation bodies, ensures their quality and active membership of international accreditation institutions supports the international recognition of conformity assessment results.

Market surveillance implemented by Member States ensures compliant products. The EU-wide market surveillance framework is implemented by Member States. National authorities know their markets best and therefore have a better sense of how to identify non-compliant products. They follow a risk-based approach to target their activities and involve all economic operators responsible for a non-compliant product, e.g. importers and distributors. They take measures that are appropriate and proportionate – including product recalls, withdrawals or public warnings – to end non-compliance or eliminate the risk posed by a non-conforming product. National authorities exchange information to increase effectiveness and avoid duplication of work.

Germany's quality infrastructure – embedded in Europe and internationally

Germany is the largest economy in the EU and its most populous country. With the German economy's focus on product quality and international orientation, Germany has been committed to the international harmonisation of quality infrastructure for many years. German experts have been actively involved in various international quality infrastructure forums, in particular on standardisation, conformity assessment, accreditation and metrology.

Standardisation. Standards are voluntary documents developed by stakeholders – particularly those in the private sector – who see a relevance and market need for them. Development of standards follows the principles of consensus, openness, transparency, coherence and non-discrimination. The German Institute for Standardization (*Deutsches Institut für Normung*, DIN) and the German Commission for Electrical, Electronic & Information Technologies of DIN and VDE (*Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE*, DKE) are the national standards bodies in Germany. They recognise the primacy of international standards and are among the most active contributors to European and international standardisation.

Conformity assessment and accreditation. There is a wide range of voluntary and mandatory conformity assessment in Germany and the EU, reflecting the various needs of an internationally oriented and modern economy. Germany's national accreditation body, Deutsche Akkreditierungsstelle GmbH (DAkkS) is a non-profit organisation with the legal status of a limited liability company. Its shareholders are the Federal Republic of Germany, the federal states and industry. While DAkkS is subject to government supervision, its accreditation decisions are made independently and impartially.

Metrology. Metrology – the science of measurement and its applications – in Germany and the EU supports international trade because it is embedded in the international metrology system. Germany and the EU are drivers behind continuous efforts to improve metrology and strengthen the international metrology network. Germany takes part in peer reviews and mutual recognition arrangements at both regional and international level. The *Physikalisch-Technische Bundesanstalt* (PTB) is Germany's National Metrology Institute. Together with three designated institutes – including the Federal Institute for Material Testing and Research (*Bundesanstalt für Materialprüfung und Testung*, BAM) – PTB is responsible for providing national measurement standards based on international definitions.

Market surveillance. The German federal states are generally responsible for enforcing market surveillance. Each state organises its own market surveillance mechanism, taking into account regional circumstances such as the underlying economic structure and existing sectoral priorities. In a few sectors, federal authorities are responsible for market surveillance – e.g. the Bundesnetzagentur (Federal Network Agency, BNetzA) for EU legislation on radio equipment and electromagnetic compatibility. To ensure uniform market surveillance across the country, the federal states coordinate their activities and exchange information closely. The German Market Surveillance Forum (*Deutsches Marktüberwachungsforum*, DMÜF) advises and supports the German Federal Government on matters of market surveillance and coordinates cross-sectoral market surveillance issues. In addition, certain coordinating tasks within the scope of the German Product Safety Act (ProdSG) have been transferred to the Central Authority of the Federal States for Safety Engineering (ZLS).

Two case studies offer practical guidance throughout the publication

In each chapter, our publication looks at two examples – a toaster and an electric motor – to illustrate key aspects of the German and European systems of quality infrastructure. Our objective is to provide answers to a range of questions: How do I know which legislation applies to which product? Where can I find standards to help me meet essential requirements? Do I need to involve a notified body for conformity assessment? And how do market surveillance authorities actually deal with dangerous products?

Overview of key quality infrastructure institutions in Germany

The appendix to this publication provides an overview of key quality infrastructure institutions in Germany: BAM, BNetzA, DAkkS, DIN, DKE, PTB and ZLS. An outline of each institution describes their mandate, services, funding and organisational structure, as well as the current focus of their work.

1. Introduction

The European Union's and Germany's quality infrastructures serve a modern and internationalised economy, while protecting people, health and the environment.

Today's consumers face many challenging questions: Is the toaster I bought safe to use? Can I trust that the brakes of the high-speed train I am riding in will not overheat? Do I know whether my mobile phone call is free from interference and tap-proof? How can I be sure that my children's toys and clothes do not contain toxic materials?
Today's economies are getting ever more complex and it seems impossible for a single person to know the answer to such questions. Therefore, an effective quality infrastructure – made up of standardisation, conformity assessment and accreditation, market surveillance, and metrology – is crucial for many aspects of our lives. A well-functioning quality infrastructure ensures product safety and consumer protection. At the same time, it performs important tasks for business and trade – both nationally and across borders.

Quality and safety in the EU: key aspects for one of the world's largest markets

The European Union (EU) is home to around 450 million people and one of the largest economic areas in the world. Companies and consumers in the EU have high quality and safety expectations of products. Companies use standards in their contracts with suppliers in the value chain to ensure they get the quality and safety they need. Consumers are increasingly becoming conscious of what they buy and not only consider the performance and safety of products, but also care about environmental, climate and health impacts, as well as labour conditions. These expectations of companies and consumers contribute to a high demand for an effective quality infrastructure in and outside the EU.

The EU single market is known as a market with legislation aiming to protect workers, consumers, the environment, and the climate in the best possible way. In many emerging regulatory fields, the EU leads the way with future-oriented legislation. Due to the importance of the EU single market in international trade, many legal requirements as well as the standards specifying those requirements have an impact beyond the EU's borders. While demanding compliance with stringent legal requirements, the EU single market is a marketplace that is attractive for businesses from in- and outside the EU. To strike this balance, the EU has developed a system which builds on the strengths of quality infrastructure. This ensures that the EU stays business-friendly and innovative while having sufficient product legislation. For example, standards are voluntary tools that businesses can use to fulfil legal requirements – but they are free to choose other technical solutions that would work too.

A success story for reducing barriers to trade: the EU single market

As the EU Member States' markets became more integrated, the EU developed its own approach to product legislation. Before the EU's integration, each country had its own rules and regulations across different areas of the economy – leading to obstacles for cross-border trade. The creation of the EU single market is therefore a success story for reducing regulatory fragmentation and easing international trade. A harmonised quality infrastructure was key to achieving this single market – through EU harmonisation legislation and supporting harmonised European standards, European standards developed by private European standardisation organisations apart from legislation, and the acceptance of each other's conformity assessment results. The EU's system has constantly been adapted and requires continuous improvements to react to new challenges.

The EU single market relies on all elements of a quality infrastructure

The EU system of quality infrastructure stands for a fair and democratic compromise between countries of widely varying size and economic structures, which takes all relevant stakeholders into account. All components of quality infrastructure are equally important as they need to work together to be effective: voluntary consensus-based standardisation, accredited conformity assessment (including testing, inspection, and certification), market surveillance by public authorities, and legal and scientific metrology that meets the needs of a modern economy. Checks and balances between the distinct parts eliminate conflicts of interest and create trust in the whole system. For example, there should be a clear distinction between the development of standards and demonstrating conformity against such standards.

In each of the pillars of quality infrastructure, the EU's approach builds on the respective strengths of the public and private sectors, academic and scientific institutions, and civil society. Public authorities can focus their resources on their key mandate: defining essential legal requirements, ensuring that companies correct or withdraw non-complying products, and imposing sanctions where needed. The private sector can pay attention to finding technical solutions that ensure compliance with legal requirements. Private businesses and all other interested stakeholders use their knowledge and experience to set standards leading the way in standardisation in the EU. The EU's approach therefore not only leads to high safety and quality, but also unburdens policymakers and drives innovation.

A system that dynamically reacts to new opportunities and challenges

The EU's approach to product legislation is designed in a way that it can constantly react to technological changes and emerging needs of the market and the public. By leaving technical details to voluntary standardisation the system is agile and can respond to change faster.[2] This is crucial in particular against the background of accelerated digitalisation. At the same time, the EU's approach itself reacts to opportunities and challenges that digitalisation entails. Online marketplaces, for example, blur the traditional lines between retailers and buyers – requiring updated roles and responsibilities in product legislation. In addition, Germany and the EU engage in the digitalisation of quality infrastructure which holds future opportunities like machine-readable standards or virtual conformity assessment procedures.

Quality and safety without borders: the importance of international cooperation

The EU promotes the international harmonisation of national quality infrastructures. Product quality and safety do not stop at the border of single countries. Global trade, cross-border value chains and international online commerce require a more global outlook to ensure product quality and safety. International trade is easier if companies do not have to fulfil different legal or technical requirements. Standards should preferably be developed at the international level as it includes the knowledge and broad acceptance from experts around the world and avoids duplication of work. Internationally recognised accreditation increases trust in conformity assessment, making repeated testing unnecessary.

2 In the EU, European standards (developed by European standardisation organisations apart from legislation) as well as harmonised European standards (developed upon request by the European Commission to support legislation) are voluntary, the latter play a crucial role for the presumption of conformity. See Chapter 4.

Germany is the most populous country and largest economy in the EU. Given the German economy's focus on quality of products and its international orientation, Germany has engaged in the international harmonisation of quality infrastructure for many years. In particular in standardisation, conformity assessment, accreditation, and metrology, German experts have been active contributors in various international quality infrastructure institutions.

Germany's Global Project Quality Infrastructure

To support the international harmonisation of quality infrastructures, the German Federal Ministry for Economic Affairs and Energy (*Bundesministerium für Wirtschaft und Energie*, BMWi) has been cooperating with international partner countries for many years. Germany consolidated and increased these efforts with the establishment of the Global Project Quality Infrastructure (GPQI) in 2017. Through GPQI, Germany engages in international cooperation on quality infrastructure with important trading partners such as Brazil, China, Mexico, India, and Indonesia. In addition, there is a cooperation with Canada, the Eurasian Economic Union (EAEU) and the United States. The political and technical dialogues bring together experts from public and private sectors, standardisation and accreditation bodies, metrology institutes, and technical-scientific institutions. All work together towards reducing technical barriers to trade, strengthening product safety, and enhancing consumer protection.

Overview of this publication

This publication shall give an easy-to-read overview of the EU's approach to quality infrastructure and its implementation in Germany. It begins with a chapter that introduces the EU's approach to product legislation and informs about basic laws. In the subsequent chapter, readers will learn about the responsibilities of the various economic actors and the key concepts for complying with product legislation, such as the presumption of conformity. The four next chapters each describe one pillar of quality infrastructure in the EU: standardisation, conformity assessment and accreditation, metrology, and market surveillance. Important quality infrastructure institutions in Germany are described in more detail in the appendix of this publication. It also includes a non-exhaustive list of recommended further readings on quality infrastructure and illustrates key aspects with two product examples.

"The international harmonisation of quality infrastructure not only helps economies all around the world to facilitate day-to-day business and to reduce costs. It is increasingly becoming an aspect of geostrategic interests and international technical collaboration to promote the successful development of highly innovative technologies such as artificial intelligence, quantum computing, network technologies or smart farming."

Stefan Schnorr, Director General Digital and Innovation Policy, BMWi

Toaster and electric motor: Two case studies to guide you through the publication

Chapter by chapter, this publication illustrates key aspects of the German and European systems of quality infrastructure using two examples – a consumer appliance and an industrial product – to help answer a range of possible questions: How do I know which pieces of legislation apply to my product? Where can I find standards to help me meet the essential requirements? Do I have to involve a notified body during conformity assessment? And what do market surveillance authorities actually do about dangerous products?

To get practical answers to these questions, you are invited to track the journey onto the EU single market of a toaster and an electric motor. At the end of each chapter, an information box will highlight relevant key points of these two case studies. Please note, however, that content may be simplified in order to fulfil the illustrative purpose – information boxes do not provide legal advice on EU market access. Given this publication's focus on quality and safety aspects of products manufactured in the EU and abroad, it does not refer to customs procedures, import duties or rules of origin. The two products in question are considered to be new products to be placed on the EU single market.

Toaster: The first case study looks at the small electrothermic appliance used by household consumers to make toast – crisp, golden brown, sliced bread – without getting an electric shock. There are around 35 million toasters in use in Germany alone.[3] The Harmonised System (HS) assigns such toaster the classification code 85 16 72 0000.

Electric motor: The second case study involves an electric motor that is used to move objects in a series of industries – from manufacturing and packaging to construction. There are around 8 billion motors in use in the EU, consuming around 50 percent of the EU's electricity production.[4] Our example describes an electric motor used with low voltage – i.e. between 50 and 1000 volts (alternating current, AC) – and with an output of more than 750 watts but not exceeding 7.5 kilowatts. The electric motor in question is not intended for use in vehicles or aircraft, nor in people's homes or special environments, such as in explosive atmospheres or liquids. The HS code for such product is 85 01 52 2000.

3 Source: https://www.statista.com/forecasts/1174519/small-kitchen-appliance-toaster-coffee-machine-ownership-rate-european-countries.

4 Source: https://ec.europa.eu/info/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign/energy-efficient-products/electric-motors_en.

2. The system of product legislation in the EU and Germany

An established system to ensure an EU single market with business-friendly market access but stringent regulation.

Key points in this chapter

- The EU created its single market through a combination of EU-wide harmonised product legislation and mutual recognition of national requirements.
- Most EU harmonised product legislation is aligned to the principles of the New Legislative Framework (NLF), mandating compliance with essential requirements but providing no technical specifications such as standards.
- Harmonised European standards are voluntary tools designed to demonstrate compliance with essential requirements.
- The use of these voluntary harmonised standards triggers the legal presumption of conformity with relevant essential requirements vis-à-vis market surveillance authorities.
- The EU's legislative approach takes into account the principles of the World Trade Organization (WTO), in particular the agreement on technical barriers to trade (TBT).

2.1. Basic legal principles in the EU

One of the EU's greatest achievements is the establishment of its single market – one of the world's largest, with 450 million consumers. In addition to the 27 EU Member States, the EU single market also extends to the European Free Trade Association (EFTA) countries Iceland, Liechtenstein, Norway and Switzerland.

The single market seeks to ensure there are no internal borders or other regulatory hurdles inhibiting the free movement of goods and services.[5] Whereas people often think of tariffs or quotas that inhibit trade, technical barriers to trade or non-tariff measures have become increasingly important. These arise from diverging legal requirements, conformity assessment procedures or (mandatory) standards etc. The EU harmonised market is generally free from these technical barriers. The legal framework described in this chapter is what makes these benefits for consumers and businesses possible.

The EU's legal framework comprises several types of laws which have a hierarchical order. At the highest level of this hierarchy, treaties lay down fundamental rules concerning the values, system and functioning of the EU. They include the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU). Based on these treaties, secondary law defines key EU legislations – including the functioning of the EU single market. Secondary law includes three important legal acts:

- **EU regulations** are binding legislative acts. They are automatically legally binding in all Member States upon entering into force.

5 Should one EU Member State issue regulations that create unnecessary barriers to trade within the EU, the other Member States may address such hurdles in court.

- **EU directives** set out goals that Member States must achieve. For this, EU members must devise their own laws to fulfil these goals. In other words, the states must transpose EU law into national law and withdraw conflicting national laws.

- **EU decisions** address certain bodies, such as one or several Member States. They are binding and directly applicable without the need to be transposed into national law.

If there is a conflict between legal acts that regulate the same matter, two principles determine which one is applicable. In general, the higher legal act establishes the framework for a lower one – this means that the lower legal act must be in line with the higher one or is otherwise invalid. In addition, the more specific legal act takes precedence. This means that more specific sectoral legislation – on pressure equipment, for example – comes before more general legislation such as Directive 2001/95/EC, the General Product Safety Directive.

2.2. Free movement in harmonised and non-harmonised sectors

Products move freely due to EU harmonisation legislation and mutual recognition

Member States are not allowed to adopt or keep additional or conflicting national requirements in sectors that are fully harmonised through EU legislation. Most products in the EU in these harmonised sectors are covered by these common rules – providing clear and uniform parameters for businesses and consumers. In these harmonised sectors, most legislative acts prescribe only essential requirements for health, safety, performance and environmental protection. This key principle of the New Legislative Framework (NLF) is explained later in this chapter. There are few sectors in which harmonised legislation continues to mandate certain technical specifications (these include chemicals, cosmetics, pharmaceuticals and motor vehicles).

If a sector is not covered by EU harmonisation legislation, the national rules of individual Member States may apply. However, the free movement of goods is ensured also in non-harmonised sectors. This is achieved through the principle of mutual recognition: any product that is lawfully sold in one Member State can be made available in another.
Only a few exceptions exist for the protection of public safety, health or the environment. Sectors of non-harmonised legislation include childcare articles and cash registers.

Please note that the EU principle of mutual recognition in non-harmonised sectors is different from the EU's agreements with third countries on the mutual recognition of conformity assessment results. Moreover, the principle is not related to mutual recognition arrangements in international accreditation (see Chapter 5).

Within the EU, national technica regulations must be notified – similar to WTO rules

In addition to the mutual recognition principle, the EU ensures the free movement of goods in non-harmonised sectors through a notification procedure. According to Directive (EU) 2015/1535, Member States must inform the European Commission of draft national technical regulations before they are adopted. The Commission or Member States can then submit concerns if they believe that the draft national regulation is not in compliance with EU law, for example by violating the free movement of goods principle. If the EU already plans harmonised legislation in the same sector, the Commission can halt the adoption of a national regulation for up to 18 months (see information box 1). This notification procedure works in a comparable

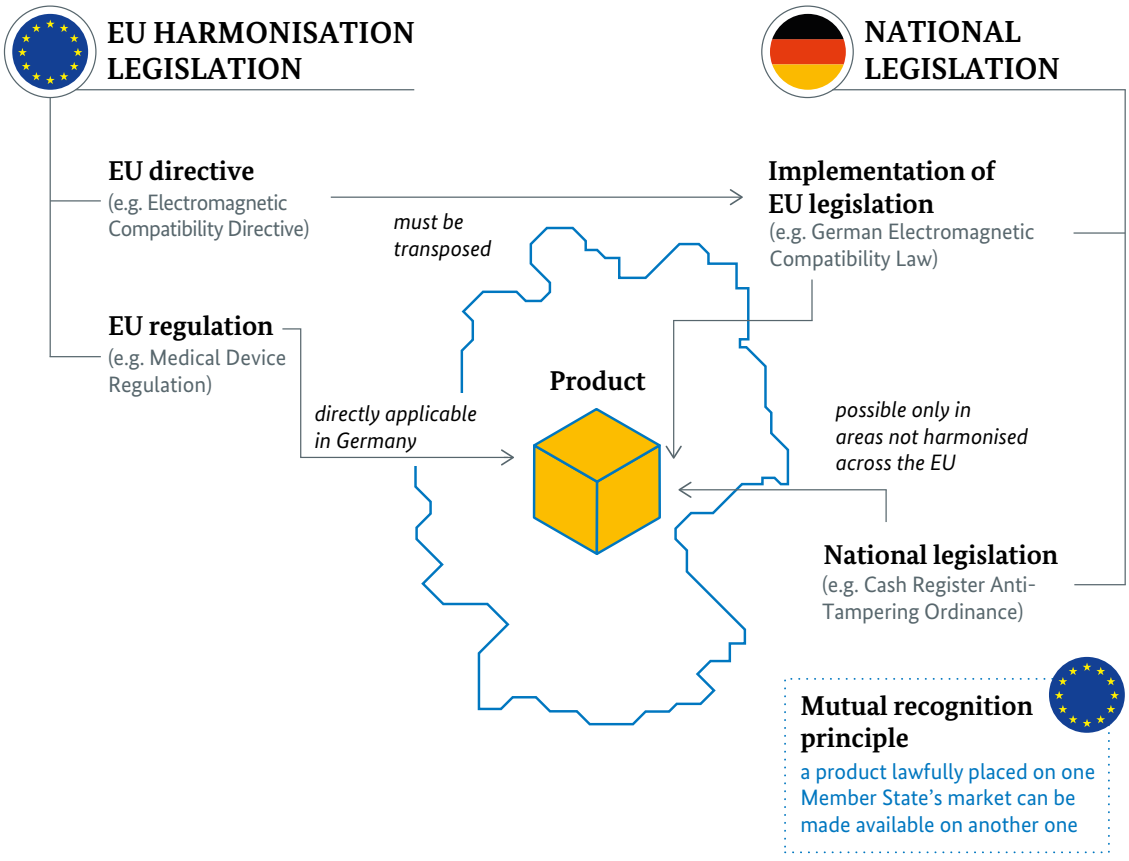
way to the notification procedure for technical barriers to trade (TBT) of the World Trade Organization (WTO). However, depending on the content, Member States must notify both the WTO and the EU of any draft technical regulations.

Information box 1: Technical Regulations Information Systems database (TRIS)

Any notifications by Member States of draft technical regulations according to Directive (EU) 2015/1525 are available on the Technical Regulations Information Systems database (TRIS). The TRIS database allows interested parties to send their comments directly to the European Commission.

The database can be accessed at: https://ec.europa.eu/growth/tools-databases/tris/en

Figure 1: Relationship between EU harmonisation legislation and national rules



2.3. The EU's legislative approach to the single market for goods

From detailed technical rules to modern and effective governance

The single market for goods builds upon a legislative approach that has been evolving over time. The EU's approach represents a modern way of governance that balances the interests of government, consumers, the environment, private businesses, and the involvement of the public sector. The development of the EU's approach followed a growing awareness that it was impractical for public authorities to mandate detailed technical requirements for the purpose of health, safety, quality or performance of goods – and other aspects of public interest. Enshrining detailed technical specifications and administrative rules in legislation made the system slow to react to technological change and constrained innovation. This development was driven also by a ruling from the European Court of Justice in 1979 – known as the *Cassis de Dijon* case – in which the court ruled that EU members may only restrict the free movement of goods if their non-compliance with essential requirements can be demonstrated.

As a consequence, in 1985 the EU introduced the New Approach to technical harmonisation for most products: EU legislation is limited to prescribing essential requirements and leaves the technical details to voluntary standards. Products can only be placed on the market if they meet these requirements, for example with regard to health, safety, the environment and other aspects of public interest (see information box 2).

Standards are voluntary tools that support legislation

EU product legislation does not include detailed technical specifications. These are defined through voluntary harmonised standards – European standards developed upon request by the European Commission to support EU harmonisation legislation (see Chapter 4.4). Unlike in many regions around the world, there are no mandatory standards in the EU unless standards are directly referenced to in laws or would be legally binding as being stipulated in private contracts.[6] Manufacturers can use any technical specifications to fulfil essential requirements. Harmonised standards are just one way – but of course a beneficial one – of achieving this. This freedom to use individual technical solutions creates space for innovation. By leaving technical details to standardisation, the approach also leads to a more stable regulatory environment, since regulators do not need to update essential requirements as often as detailed technical standards. The result is a predictable, transparent and hence favourable business environment.

One might wonder why companies use harmonised standards if they are not mandatory. The use of harmonised standards has several advantages. As with any standard, harmonised standards allow companies to apply solutions developed by leading experts in the field saving valuable costs and time.

In the EU, applying a harmonised standard has the additional advantage that a product benefits from a presumption of conformity with the corresponding essential requirements vis-à-vis market surveillance authorities.

6 One example for exception is in the area of the Construction Regulation.

Information box 2: Essential requirements in EU harmonisation legislation

Essential requirements are designed to achieve the protection of public interest. They are either developed because of inherent product hazards – such as flammability, chemical or biological characteristics – or set out the principal protection objective. They might also refer directly to the product or its performance – such as its material composition, design, construction or manufacturing process. Products may have to comply with several essential requirements from various pieces of EU legislation (the LV and EMC directives). The manufacturer identifies which essential requirements the product must fulfil through a risk analysis undertaken during conformity assessment (see Chapter 3).

When formulating essential requirements, EU legislators need to strike a balance: essential requirements should be specific enough to allow for verifiable protection of public interests, yet vague enough to allow for different technical solutions. They therefore vary in their degree of detail depending on the matter in hand. However, in no circumstances do they specify detailed technical solutions, such as those concerning manufacturing processes. Essential requirements can be found in the main body of the legislative acts or in their annexes.

Example: Essential requirements for electromagnetic compatibility

Annex 1 of the Directive 2014/30/EU on electromagnetic compatibility specifies the following essential requirements:

1. General requirements

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

2. Specific requirements for fixed installations

Installation and intended use of components

a) A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in point 1.

A word on the difference between quality and safety

In Germany – and the EU in general – quality and safety are traditionally treated as quite separate things.

Quality may relate to various aspects of a product, such as its functionality, durability and performance. People may have different views on which aspects are more important than others. In other words: quality is subjective. So, it is largely a matter determined by market forces without government intervention. Voluntary standards and conformity assessments may serve to show users that a product has a certain quality.

When it comes to **safety** – and other aspects of public interest such as environmental protection or electromagnetic compatibility – the government steps in to protect consumers and workers. Here, the legislator defines legislative requirements which products must fulfil. These cannot be left to the market because public's health is at stake.

This means that manufacturers have less work to document how their products meet essential requirements. If manufacturers apply harmonised standards, market surveillance authorities presume that the products conform with legal requirements covered by the standards and need to establish evidence of a product's non-compliance. In other words: the burden of proof is reversed. It may also be beneficial in cases of product liability – in particular because the use of harmonised standards makes non-conformity less likely, thus reducing the possibility of a liability claim. However, the use of harmonised standards does not in itself imply exemption from a manufacturer's liability. In some instances, the use of harmonised standards also leads to simpler conformity assessment procedures (see Chapter 3).

Trust through a coherent set of conformity assessment modules

To increase trust in the system of essential requirements and harmonised standards, the EU introduced a 'horizontal menu' of conformity assessment modules – a menu of conformity assessment options that can be applied for different kinds of legislation.[7] Based on the modules described in Decision No 768/2008/EC, the European legislator selects the conformity assessment procedure that is appropriate for a given product – while always trying to choose the one that is least burdensome for businesses. For this, the European legislator considers factors such as the type of product, potential hazards involved, and the required level of protection of public interest. The EU ensures a coherent and consistent use of conformity assessment in legislation by setting out the modules in Decision No 768/2008/EC.

7 This addition to the New Approach is commonly referred to as the Global Approach, based on the Resolution by the Council on the Global Approach and Decision 90/683/EEC. This Decision was since updated and replaced by Decision 93/465/EEC and then by Decision No 768/2008/EC.

The conformity assessment modules cover both design and production phases. They range from internal production control to conformity based on full quality assurance plus design examination. Conformity assessment is the responsibility of the manufacturer, regardless of the involvement of a third-party conformity assessment body. Please refer to Chapter 3.2 for details on conformity assessment modules.

The EU's quality infrastructure system is designed to create trust, business-friendly market access, stringent enforcement of regulation, high product safety and protection of other aspects of public interest. All elements of the EU quality chain are interlinked and work together to ensure this.

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 brought in to complement and strengthen the EU's approach to product legislation of the single market. The NLF continues the proven method that uses a combination of essential requirements and harmonised standards introduced through the New Approach. Taken together, the New Approach and NLF define key characteristics of the EU's single market for goods.

The NLF strengthens the overall coherence and consistency of EU legislation, the notification process, accreditation, conformity assessment procedures and market surveillance. It comprises three basic legal acts, of which one will be amended in 2021:

1. **Requirements for accreditation and market surveillance of products** are set out in Regulation (EC) No 765/2008. This regulation will be amended with Regulation (EU) 2019/1020 on market surveillance and compliance of products, which for example improves market surveillance for products sold online (e-commerce). The amendment entered into force between January and July 2021.[8]

2. A **common framework for the marketing of products** was established with Decision No 768/2008/EC. This legal act can be seen as a template for the alignment of current and future product legislation: it provides general principles and reference provisions for harmonisation legislation within the EU. It covers aspects such as definitions, criteria for the designation and notification of conformity assessment bodies, rules for the notification process, conformity assessment modules, responsibilities of the economic operators and traceability requirements.

3. The **mutual recognition principle** is set out in Regulation (EU) 2019/515. It regulates procedures for the application of national technical rules to products lawfully marketed in another Member State. It came into effect on 19 April 2020 and replaced Regulation (EC) No 764/2008.

8 The legal acts which updated the New Legislative Framework in 2019 are commonly referred to as the 'Goods Package' (namely Regulation (EU) 2019/515 and Regulation (EU) 1020/2019).

The NLF strengthens crucial elements of the EU's quality infrastructure. It acts as a comprehensive and coherent legislative system for product safety and the protection of other public interests that can be used across sectors. The NLF strengthens accreditation and market surveillance and thereby complements the EU's quality infrastructure.

Layers of public control: accreditation and market surveillance

Regulation (EC) No 765/2008 established a comprehensive legal basis for accreditation and market surveillance as effective layers of public control.

While conformity assessment bodies are mostly private entities, accreditation bodies are publicly authorised and supervised. Their function within the system of quality infrastructure is to attest the technical competence of conformity assessment bodies. There is only one national accreditation body per Member State and competition between them is not allowed. This quasi-monopolistic position is designed to avoid harmful competition that could potentially encroach on the quality of accreditation itself. It thus ensures a coherent system that generates trust in conformity assessment throughout Europe. By following international standards for accreditation and international recognition arrangements, accreditation also eases the cross-border flow of goods and services (see Chapter 5).

Information box 3: The EU's approach to harmonised legislation for products at a glance

1. Products made available on the EU single market shall **conform to EU product legislation**.
2. By affixing the **CE marking** and issuing the **EU declaration of conformity**, manufacturers declare that a product meets all legal requirements for CE marking and can be sold throughout the European Economic Area.
3. EU harmonisation legislation is limited to the **essential requirements**.
4. **Harmonised standards** lay down technical specifications for detailing the essential requirements.
5. **Applying harmonised standards is voluntary** and other technical specifications are possible.
6. Using harmonised standards leads to a **presumption of conformity** with the corresponding essential requirements vis-à-vis the market surveillance authorities.
7. The **manufacturer is responsible** for performing an initial risk assessment and demonstrating compliance with essential requirements through **conformity assessment**.
8. EU legislation chooses from a 'horizontal menu' of **conformity assessment modules** which fits varying requirements.

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Information box 3: The EU's approach to harmonised legislation for products at a glance (cont.)

9. Coherence of EU harmonisation legislation by **alignment to NLF reference provisions**.
10. Clear **definition of the roles and responsibilities of economic operators** in the supply chain.
11. Post-**market surveillance** as an element of public control.
12. Clear and transparent rules on **publicly authorised accreditation** of conformity assessment bodies.
13. **Mutual recognition** principle: a product lawfully marketed in one country cannot be restricted from free movement throughout the entire single market.

Market surveillance is another layer of public control. It ensures that products on the EU market do not endanger consumers and workers and are otherwise compliant with legal and administrative requirements. Market surveillance should not be confused with conformity assessment. This takes place before a product is placed on the market, whereas market surveillance begins with a product's market entry. Individual EU members are responsible for market surveillance in their territory, for example drawing of product samples to verify their conformity (see Chapter 7).

Key aspects of the EU's approach to product legislation are summarised in information box 3.

2.4. Scope of EU product legislation

A level playing field without a list of regulated products or mandatory standards

EU harmonisation legislation applies to products placed on the EU single market and to any step involved in making them available to their end-users. According to EU harmonisation legislation,[9] end-users are not 'economic operators'. They therefore have no responsibilities under this legal framework. Harmonisation legislation applies only to products destined to be placed on the EU single market. The EU system does not differentiate between products manufactured within borders of the EU single market and those manufactured outside – thus creating a level playing field with international trade partners. There is no requirement for products manufactured within borders of the EU single market and intended solely for export to third countries to comply with EU harmonisation legislation.

9 The term used in official EU documents is usually 'Union harmonisation legislation'. To improve clarity for international readers, the term used in this publication is 'EU harmonisation legislation' also compared to the global term 'technical regulation'.

There is no official list of products regulated in the EU, nor is there a list of mandatory standards. There are two reasons for this: legislation in general only mandates essential requirements; and the use of harmonised standards is voluntary.[10]
All legal requirements with which products must comply are either defined in general product safety or sector-specific legislation.

Simple general rule: products must be safe

The General Product Safety Directive (GPSD)[11] requires that only safe products can be placed on the single market. It covers any product that is intended for use by consumers or is likely to be used by them – even if this was not the intent. GPSD establishes an overarching legal basis for product safety, acknowledging that it is not possible to cover every product category with sector-specific legislation. The directive applies insofar as there are no additional specific provisions in EU legislation covering the same aspects and risks (for example as in the sector-specific directives for toys or electrical equipment). GPSD is a key legislation ensuring product safety within the EU. GPSD is not strictly part of the NLF but also follows the principle in terms of prescribing only essential product safety rules.[12]

EU directives must be implemented in national legislation before becoming legally binding in Member States. In Germany, the German Product Safety Act (*Produktsicherheitsgesetz*, ProdSG) transposes GPSD and other EU single market directives into national law. As with GPSD, ProdSG applies insofar as there are no other legal provisions stipulating corresponding or more extensive requirements to ensure consumer health and safety. Accordingly, other legislation (e.g. sectoral laws) always takes precedence where it contains at least corresponding provisions. Should other legal provisions regulate only specific aspects, ProdSG shall also be applied to cover such omissions.

Sectoral product legislation is widely harmonised across the EU

Most product legislation is harmonised across the EU and few national rules exist (in such cases, free movement of goods is ensured by the mutual recognition principle, as described in Chapter 2.2). The majority of EU harmonisation legislation is aligned to NLF principles.[13] This means that such legal acts follow the same logic, including the use of essential requirements, voluntary use of harmonised standards, and choice of conformity assessment from the 'horizontal menu' of modules. To date, 23 legislative acts are aligned to the NLF provisions (see information box 4).[14]

In a few sectors, legislation has not been aligned to the NLF. In areas such as motor vehicles and chemical products, legislation follows the 'Old Approach', which stipulates that certain products must meet the same detailed technical specifications. One reason for this is that some sectors, such as the automotive industry, are governed by international regulatory arrangements which predate the NLF and which the EU cannot change unilaterally (e.g. automotive regulations defined by the United Nations Economic Commission for Europe, UNECE). In other areas, alignment of legislation to the NLF is still in process.

10 As previously indicated, there are a few exceptions in sectors such as construction products, where mandatory standards do exist.

11 Directive 2001/95/EC

12 GPSD is currently under review; a revision may be published in the future.

13 For this reason, this publication mostly refers to EU harmonisation legislation that is aligned to the NLF principles.

14 Regulation (EU) 1020/2019 on new market surveillance will be applicable to 70 legislative acts.

2.5. The EU's approach to product legislation and global trade

The EU is not only one of the largest markets in the world, it also has a strong voice in international trade. The continent is deeply integrated into international markets. In 2018, the EU was the world's second largest importer (first was the United States) and exporter of goods (first was China).[15] The EU's open market is a key reason for its strong role in international trade. As described above, the EU single market does not distinguish between products manufactured inside or outside the EU: it provides a level playing field with common rules for all. The NLF has also eased market access for foreign businesses by allowing individual manufacturers to come up with technical solutions of their own to fulfil product requirements. Many products simply require the manufacturer's declaration of conformity for CE marking (see Chapter 3.6). This enables easier market access compared with the mandatory certification requirements or pre-market approvals that are still common in many countries globally.

The EU advocates a rules-based multilateral trading system and is actively involved in the Committee on Technical Barriers to Trade (TBT) of the World Trade Organization (WTO). As outlined above, the EU has established a notification system for national rules among its members which is similar to the WTO's TBT notification procedure – through which WTO members inform other members of draft legislation that could potentially create a technical barrier to trade. The EU's notification system exists in parallel to the WTO TBT system, as it relates to the notification of EU Member States' technical regulations which could create trade barriers for other members.

Information box 4: EU harmonisation legislation aligned to the provisions of the New Legislative Framework (non-exhaustive list)

1. **Toy safety** – Directive 2009/48/EU
2. **Transportable pressure equipment** – Directive 2010/35/EU
3. **Restriction of hazardous substances in electrical and electronic equipment** – Directive 2011/65/EU
4. **Construction products** – Regulation (EU) No 305/2011
5. **Pyrotechnic articles** – Directive 2013/29/EU
6. **Recreational craft and personal watercraft** – Directive 2013/53/EU

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15 Source: https://ec.europa.eu/eurostat/statistics-explained/index.php/International_trade_in_goods_for_the_EU_-_an_overview" \l "International_trade_in_goods_-_an_overview

Information box 4: EU harmonisation legislation aligned to the provisions of the New Legislative Framework (non-exhaustive list) (cont.)

7. **Civil explosives** – Directive 2014/28/EU
8. **Simple pressure vessels** – Directive 2014/29/EU
9. **Electromagnetic compatibility** – Directive 2014/30/EU
10. **Non-automatic weighing instruments** – Directive 2014/31/EU
11. **Measuring instruments** – Directive 2014/32/EU
12. **Lifts** – Directive 2014/33/EU
13. **ATEX** – Directive 2014/34/EU (related to equipment and protective systems intended for use in potentially explosive atmospheres)
14. **Low voltage** – Directive 2014/35/EU
15. **Radio equipment** – Directive 2014/53/EU
16. **Pressure equipment** – Directive 2014/68/EU
17. **Marine equipment** – Directive 2014/90/EU
18. **Cableway installations** – Regulation (EU) 2016/424
19. **Personal protective equipment** – Regulation (EU) 2016/425
20. **Gas appliances** – Regulation (EU) 2016/426
21. **Medical devices** – Regulation (EU) 2017/745
22. **In vitro diagnostic medical devices** – Regulation (EU) 2017/746
23. **EU fertilising products** – Regulation (EU) 2019/1009

To implement the WTO TBT Agreement and its notification procedure, the EU set up a TBT Enquiry Point at the European Commission and, in addition, Member States subsequently set up their own enquiry points. EU Member States notify technical regulations or conformity assessment procedures directly to the WTO and inform the European Commission's TBT contact point. However, if a third country comments on one of the EU's notifications, the European Commission answers this on behalf of the EU – in close cooperation with the EU member concerned. This system ensures that the EU speaks with one voice internationally and that third countries have a designated point of contact for all EU matters.

In Germany, the German Federal Ministry for Economic Affairs and Energy (BMWi) has handed responsibility for running the TBT Enquiry Point to the German Institute for Standardization (DIN), which is supported in fulfilling its task by the German Accreditation Body (DAkkS). Companies in third countries are invited to contact the TBT Enquiry Point for further information on notified technical regulations, and German companies can enquire about notifications from other countries – both can be done free of charge.

Recognising important economic transformations such as the globalisation of value chains and digitalisation of the economy, the EU places emphasis on complementing multilateral rules with trade agreements that include provisions on non-tariff barriers. In addition, the EU has signed several bilateral mutual recognition arrangements (MRAs), including those with Australia, Canada, Japan and the United States. MRAs facilitate the recognition of conformity assessment results and thereby ease market access (see Chapter 5 for a disambiguation of MRAs). In some cases, these MRAs are part of free trade agreements – e.g. as in the Comprehensive Economic and Trade Agreement (CETA) between Canada and the EU – or are stand-alone agreements.

Contacting the German TBT Enquiry Point

Please contact the TBT Enquiry Point if you would like to receive information on specific regulations in Germany. You are also invited to reach out to the TBT Enquiry Point if you represent a German company and have product-specific questions about technical regulations in a third country.

Enquiries are free of charge and answered only in writing by email. Please contact the German TBT Enquiry Point at: auskunft@din.de

Case studies: Which EU legislation applies to my product?

As this chapter makes clear, it is the manufacturer's responsibility to ensure that a product complies with applicable legislation – this is mostly harmonised throughout the EU. In a few cases, national requirements apply, but the mutual recognition principle guarantees that a product sold lawfully in one country can move freely within the EU single market.

There are two useful official resources to help companies identify which pieces of legislation apply to a product. The EU helpdesk **Access2Markets** (trade.ec.europa.eu/tradehelp) is the EU's one-stop-shop to inform companies about import rules and regulations, duties and rules of origin for specific products. 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:

Product scope	Contact point
Investment and consumer goods and other products	Federal Institute for Materials Research and Testing (*Bundesanstalt für Materialforschung und -prüfung*, BAM)
Food, agricultural and fisheries products and commodities	Federal Agency for Agriculture and Food (*Bundesanstalt für Landwirtschaft und Ernährung*, BLE)
Construction products	German Institute for Structural Engineering (*Deutsches Institut für Bautechnik*, DIBt)

Toaster

Before we can start making toast, our kitchen appliance must meet the requirements set out in EU legislation. These include three directives which use the CE marking and additional legislation requiring two other markings:[16]

Legislation using the CE marking:

- **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). In line with these requirements, the toaster must safeguard the protection of persons and domestic animals from any risk arising from its use. 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).

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16 This publication disregards the Ecodesign Directive 2009/125/EC here due to its low relevance for the majority of toasters.

- **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).

- **Electromagnetic compatibility.** As with any electric appliance, a toaster creates an electromagnetic field that may interfere with other electric equipment. The toaster must therefore comply with the Electromagnetic Compatibility (EMC) Directive 2014/30/EU, which provides essential requirements in its Annex I. In line with these requirements, the toaster must be designed and manufactured in such a way that electromagnetic emissions do not prevent other electrical equipment or other devices from being operated as intended. Furthermore, the toaster must have a level of immunity to electromagnetic disturbance which enables 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).

Further requirements:

- **Requirements for articles in contact with food.** The toaster must comply with Regulation (EC) No 1935/2004 which mandates that any material or article intended to come into contact with food must preclude that substances 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 use the symbol depicting a glass and fork (right).

Image 1: Label indicating material or article for food contact (in compliance with Regulation (EC) No 1935/2004)

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

Image 2: Label informing consumers that they shall not throw an electrical or electronic equipment in the household garbage.

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Electric motor

As an industrial product, an electric motor must meet legislative requirements that differ from the toaster – but there are some overlaps. The applicable legislation depends a lot on the motor's specifications as well as its intended use. For example, an electric motor intended for use in explosive atmospheres must comply with the ATEX directive (the abbreviation derives from the French term for equipment intended for use in explosive atmospheres). The applicable legislation also depends on whether the electric motor is a stand-alone device or used as part of a machine. The electric motor must comply with three directives which use the CE marking:

Legislation using the CE marking:

- **Electromagnetic compatibility.** As an electrical appliance, the electric motor must comply with the Electromagnetic Compatibility (EMC) Directive 2014/30/EU (see page 36).

- **Low voltage electrical equipment.** The hazards for an electric motor in an industrial setting are quite different from those of a toaster. However, the manufacturer must observe the same essential requirements for the safety of low voltage electrical equipment. For example, the motor must not endanger persons, domestic animals or property in foreseeable conditions of overload.

- **Ecodesign requirements for electric motors.** By adopting Regulation (EC) No 640/2009, the EU implemented the Ecodesign Directive 2009/125/EC for electric motors. Electric motors that fall within the scope of this regulation must meet energy efficiency requirements defined in Annex I – this is crucial, given that electric motors use around half of the electricity generated in the EU. This piece of legislation defines the energy efficiency levels which certain types of electric motors must meet. Energy efficiency is expressed using the International Energy efficiency classes (IE). These range from the strictest IE4 to the lowest IE1 and are defined by EN IEC 60034-30. Under current legislation, our motor's power falls in the range between 0.75 kW and 375 kW; it must therefore have an efficiency level of at least IE3 or IE2 if equipped with a variable speed drive. As of July 2021, the new Regulation (EU) 2019/1781 replaces Regulation (EC) No 640/2009, introducing stricter requirements and expanding the product scope.

3. Complying with EU product legislation

Compliance procedures are based on a product's risk and range from self-declaration of conformity to third-party conformity assessment.

Key points in this chapter

- The New Legislative Framework (NLF) defines clear roles for all economic operators in the supply chain to ensure products are safe and follow legislation.
- Conformity assessment is the responsibility of the manufacturer, irrespective of whether a third-party body is involved or not.
- With CE marking and issuing an EU declaration of conformity, a manufacturer declares that a product conforms to all applicable EU harmonisation legislation. The CE marking is not a quality indicator or a certificate and does not necessarily imply that a third party has carried out a conformity assessment of the product. It is directed at market surveillance authorities.
- For some products, manufacturers must involve a third-party conformity assessment body (*notified body*) which has been designated by national authorities.

3.1. Actors in the New Legislative Framework

The New Legislative Framework (NLF) clearly defines the roles and responsibilities of all actors (economic operators) involved in the supply chain: manufacturers, authorised representatives, distributors, importers and fulfilment service providers.[17]

If a product is non-compliant, market surveillance authorities may take legal or administrative action against any of these economic operators. This is necessary to ensure that the EU single market is open to all products without the need for onerous controls before they are made available on the market.[18] Market surveillance only takes place after a product has been placed on the market. For this reason, the obligations of all actors in the supply chain are crucial to the EU's system of product safety.

Manufacturers: fully responsible for products that carry their name or trade mark

The manufacturer is the natural or legal person who manufactures a product or has a product made or designed and who places it on the market under their own name or trade mark.[19] This means that whoever places a product on the market under their own name or trade mark is considered a manufacturer – even if they have not 'manufactured' or 'made' the product in a narrow sense. They are then fully responsible for the product's conformity assessment.

17 Fulfilment service providers are a new category effective from June 2021 onwards. The category mainly refers to e-commerce platforms (see details pages 42/43).

18 As described in the previous chapter, some sectors are still governed by legislation based on the Old Approach that include detailed technical specifications. In addition, some of these Old Approach sectors demand pre-market approvals. For example, manufacturers of motor vehicles require a type approval (homologation) before they can produce vehicles to be placed on the EU single market.

19 The following pages make use of the European Commission's 2016 edition of the 'Blue Guide' on the implementation of EU products rules. It is available in several EU languages at https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en.

Whoever changes a product in a way that affects its conformity – and therefore its compliance with essential requirements – is also considered to be the manufacturer. The manufacturer's obligations are the same, regardless of whether the manufacturer is established inside or outside the EU. The EU treats domestic and foreign manufacturers equally (see Chapter 2). A manufacturer who subcontracts activities is still wholly responsible.

The manufacturer has full responsibility for the conformity of a product. These responsibilities include:[20]

- ensuring that conformity assessment is carried out based on the relevant legislation;
- drawing up the technical documentation and EU declaration of conformity;
- affixing the conformity marking according to the applicable legislation;
- ensuring that instructions and safety information accompany the product (if required);
- obeying traceability requirements;
- taking corrective actions in case of non-conformity and immediately informing the responsible national authorities if a product may present a risk to public interests.

Authorised representative: is appointed to share administrative obligations

Any manufacturer may appoint an authorised representative to take over certain administrative obligations on their behalf. It is irrelevant whether the manufacturer is established in the EU or not. Foreign manufacturers may – but are not obliged to – nominate an authorised representative in the EU to support them in carrying out certain tasks. However, a commercial representative of the manufacturer, such as an authorised distributor or agent, is not automatically an authorised representative according to EU legislation – the authorised representative needs to be explicitly appointed as such according to EU legislation.

EU legislation describes minimum requirements for the delegation of duties to an authorised representative. If appointed, the representative must at a minimum keep copies of the EU declaration of conformity and technical documentation and must cooperate with national authorities. Should the relevant EU sectoral legislation allow, the representative may also assume responsibility for affixing the conformity marking (e.g. CE marking), as well as preparing and signing the EU declaration of conformity.

Manufacturers may not delegate major obligations. For example, the manufacturer may not pass on to the authorised representative responsibility for ensuring that the manufacturing process assures compliance of products with legislation. The manufacturer and authorised representative must set out the delegation of duties in writing and must explicitly define the content and scope of the delegated tasks. The authorised representative can also be the importer or distributor but then the obligations for importers and distributors need to be fulfilled as well (see details below).

20 This is a simplified list of the manufacturer's responsibilities. Please refer to the applicable legislation for full information. Under some sectoral EU harmonisation legislation, the manufacturer also has additional obligations or the actual manufacturer's obligations are transferred to another actor in the supply chain.

Information box 5: Product liability vs. responsibilities for compliance with EU legislation

Please note that economic operators' **responsibilities for product compliance should not be confused with their liability for defective products**. In practice, product liability and the responsibility for a product's compliance with legislation may affect the same actors – legally, however, they are different.

EU legislation for product liability is primarily defined in Directive 85/374/EEC.[21] This directive allows people injured by defective products to **claim compensation** if they can **prove the damage and that it resulted from the defect**. However, they **do not have to prove the producer's negligence**. In Germany, the directive was transposed into national law through the German Product Liability Act (*Produkthaftungsgesetz, ProdHaftG*).

The directive holds the **producer** of a product responsible. This refers to the manufacturer of a finished product or component, as well as any person who puts their name or trade mark on the product.[22] In addition, the **importer** of a defective product into the EU single market is held accountable in the same way as its producer. If the producer cannot be identified, each **supplier** of the product may also be liable.

Producers are not liable if they were not responsible for putting the product into circulation or if it is likely that the defect did not exist when the product entered circulation. Furthermore, the producer is not liable if the defect is due to compliance of the product with mandatory regulations issued by public authorities. **This does not mean that the use of harmonised standards – and therefore the presumption of conformity – necessarily lead to a reduction in the producer's liability.** However, the use of harmonised standards may make products safer and thereby reduce the likelihood that a producer faces a liability lawsuit because of a defective product.

In the EU, generally speaking, **manufacturers have a relatively large degree of freedom in ensuring compliance** of their products with legislation (e.g. the manufacturer's declaration of conformity). However, this **is balanced with an effective market surveillance system and stringent product liability legislation** that holds producers accountable for defective products.

21 In 1999, the scope of liability was extended to agricultural and fishery products through Directive 1999/34/EC.

22 This is a simplified definition of the legal text. Please refer to the official text of Directive 85/374/EEC for detailed information.

Importer: must ensure that foreign manufacturers meet their obligations

The importer is the natural or legal person that places a product from a third country on the EU single market. They must be established in the EU. The importer has key obligations under EU harmonisation legislation similar to the manufacturer's responsibilities. They not only sell products on the EU market, they must also ensure that the manufacturer has fulfilled the applicable obligations. The importer is not required to sign a contract with the manufacturer, as is the case with the authorised representative.[23]

The importer must ensure that the manufacturer has implemented the appropriate conformity assessment procedure. This may involve contacting the manufacturer for clarification in cases of doubt. Moreover, the importer must ensure that the manufacturer has prepared the technical documentation, affixed the relevant conformity marking (e.g. CE marking), fulfilled traceability obligations, and provided accompanying product instructions and safety information in the correct language (where applicable).

Furthermore, the importer must perform additional tasks, such as visibly placing their name, registered trade mark and address on the product (or on packaging or accompanying documents). They must prevent the product from becoming non-compliant, for example as a result of incorrect storage or transport conditions.

Distributor: makes products available on the market and is a key contact for authorities

The distributor is the natural or legal person that makes a product available on the market. The distributor is different to the manufacturer, importer or authorised representative. The distributor buys products for further distribution either from a manufacturer, an importer or another distributor.

Distributors play a crucial role in ensuring the safety of products. Market surveillance authorities may request technical documentation from distributors directly. Accordingly, distributors must not supply a product if they know – or should have known – that a product is non-compliant or presents a risk to public interests.

The distributor must ensure that formal requirements are fulfilled. They must verify that the product bears the required conformity marking (e.g. CE marking), ensure that the product is accompanied by the relevant documentation (e.g. EU declaration of conformity), and check whether manufacturers and importers have provided their contact information on the product and fulfilled their traceability requirements. They must also initiate corrective actions if they suspect a non-conformity or risk, and must cooperate with authorities, for example by providing any information requested and by identifying other economic operators.[24] As is the case with importers, the distributor must take all necessary measures to protect a product's compliance, for example during storage and transport.

23 Should the importer assume additional responsibilities, they must then become an authorised representative and will be treated as such.

24 Information regarding other economic operators must be kept available for a period of ten years after the distributor has supplied or been supplied with the product.

Fulfilment service provider: the EU holds e-commerce platforms responsible for product compliance

In 2019, the EU added 'fulfilment service providers' as a further category of economic operators under EU harmonisation legislation.[25] It did so to adapt to the challenges of increasingly complex supply chains, particularly cross-border e-commerce. For market surveillance authorities, this had been a growing problem in cases where neither the manufacturer, nor the importer, nor the distributor were established within the EU. People buying foreign products on e-commerce platforms were acting as importers. Naturally, they could not be held responsible for the compliance of any products they bought. In addition, e-commerce providers did not fit into the traditional categories of economic operators – which left no economic operator accessible for the market surveillance authorities.

The EU therefore introduced the category of fulfilment service providers. These are any natural or legal persons who commercially offer at least two of the following services: warehousing, packaging, addressing and dispatching – without having ownership of the products involved. The definition excludes postal services and thus mainly refers to e-commerce platforms.

For certain legal acts under EU harmonisation legislation, at least one economic operator must be established in the EU.[26] Where the service fulfilment provider is the only economic operator established in the EU, they can be held accountable for compliance of the product made available on the EU single market.

Fulfilment service providers must ensure that the EU declaration of conformity and technical documentation have been drafted, must report to market surveillance authorities any products that pose risks and must help to eliminate those risks. They must also indicate their name or trade mark on the product, packaging or accompanying documents.

3.2. Conformity assessment under EU harmonisation legislation

This subchapter describes conformity assessment applicable to products which fall under EU harmonisation legislation. Conformity assessment in a broader sense is described in Chapter 5, including the relationship with accreditation and the voluntary use of third-party conformity assessment.

According to EU product legislation, the manufacturer must carry out conformity assessment procedures before a product is placed on the market. With conformity assessment, the manufacturer demonstrates that a product conforms to applicable legislative requirements, i.e. essential requirements.

25 This was enacted through Regulation (EU) 1020/2019 (the new market surveillance regulation).

26 According to Article 4 (5) of Regulation (EU) 2019/1020: Regulations (EU) No 305/2011 (on marketing of construction products), (EU) 2016/425 (on personal protective equipment) and (EU) 2016/426 (on appliances burning gaseous fuels) of the European Parliament and of the Council, and Directives 2000/14/EC (noise emission in the environment by equipment for use outdoors), 2006/42/EC (on machinery), 2009/48/EC (on the safety of toys), 2009/125/EC (on ecodesign), 2011/65/EU (on the use of certain hazardous substances in electrical and electronic equipment), 2013/29/EU (on pyrotechnic articles), 2013/53/EU (on recreational craft and personal watercraft), 2014/29/EU (on simple pressure vessels), 2014/30/EU (on electromagnetic compatibility), 2014/31/EU (on non-automatic weighing instruments), 2014/32/EU (measuring instruments), 2014/34/EU (on equipment and protective systems intended for use in potentially explosive atmospheres), 2014/35/EU (on electrical equipment designed for use within certain voltage limits), 2014/53/EU (on radio equipment) and 2014/68/EU (on pressure equipment).

Conformity assessment is the sole responsibility of manufacturers and is carried out by them. This is regardless of whether a third-party conformity assessment body is involved in the process – which is not always the case. While assuming overall responsibility, the manufacturer may hand over some steps of the conformity assessment to the authorised representative (see details pages 47/48).

The applicable legislation lays down which procedures from the 'horizontal menu' of conformity assessment modules a product must undergo. The horizontal menu comprises eight modules; these are described in greater detail below. Not all modules demand the involvement of a third-party conformity assessment body (i.e. notified body). There are three broad possibilities, based on the different modules:

1. **manufacturer's declaration of conformity** with no involvement of a third-party conformity assessment body;

2. **involvement of an accredited in-house conformity assessment body** that forms an independent part of the manufacturer's organisation;[27]

3. **involvement of a third-party conformity assessment body** (i.e. notified body).

Conformity assessment fit for purpose: the EU's 'horizontal menu'

The horizontal menu of conformity assessment procedures includes eight different modules (A to H). This approach creates a coherent and limited set of procedures which can be applied to a wide range of products. The modules relate to the design phase of products, their production phase, or both (see Table 1).

Some of the modules have variants, or submodules, to achieve the necessary safety level for products with a higher risk. The eight modules and their eight variants can be combined with each other in numerous ways to establish conformity assessment procedures that achieve the required level of protection. Based on the related risk for safety, health and environment, EU legislation determines the required modules. It is supposed to apply in each case the conformity assessment procedure which creates the least burden on the manufacturer.

Conformity assessment procedures may cover the design and production phases with one module (e.g. A, G or H) or two modules (e.g. combining B+C). Such two-module procedures require conformity assessment based on EU type examination and will therefore always involve module B during the design phase (see Table 1). Type examination means that the conformity of a specimen or design of a product is examined first. Subsequently, conformity of the product is checked based on that approved specimen. This saves time and costs, in particular for mass produced products.

Modules D, E, and H make use of quality assurance techniques derived from EN ISO 9000 and EN ISO 9001. While reference to these standards leads to a presumption of conformity with the relevant essential requirements, the manufacturer may choose other approaches for their quality assurance system.

27 The accredited in-house body must be independent of any commercial, design or production entities of the manufacturer. It must demonstrate the same technical competence and impartiality as third-party conformity assessment bodies. In the case of in-house conformity bodies, the EU recognises that in innovative and complex sectors in particular, the manufacturer may have testing and control capabilities which external third-party conformity assessment bodies may not provide.

Table 1: Overview of conformity assessment modules and requirements to involve a notified body

Design Phase	Production Phase
Module A – Internal production control (Depending on variant: no notified body required or choice* between notified body and in-house accredited body)	
Module B – Type examination (notified body required)	**Module C – Conformity to type** (Depending on variant: no notified body required or choice* between notified body and in-house accredited body)
	Module D – Production quality assurance (notified body required)
	Module E – Product quality assurance (notified body required)
	Module F – Product verification (notified body required)
Module G – Unit verification (notified body required)	
Module H – Full quality assurance (notified body required)	

* the choice may be restricted through the applicable legislation

Source: Adapted from EU 'Blue Guide' 2016.

3.3. Technical documentation and the presumption of conformity

Documenting a product's risks, applicable legal requirements and how these are met

According to EU harmonisation legislation, manufacturers must draw up technical documentation which shows how a product meets applicable requirements. It provides information on the design, manufacturing and operation of the product, as well as other details. The exact content depends on the legislation relevant to the product. The technical documentation must be available as soon as the product is placed on the EU single market. If a market surveillance authority requests technical documentation, the manufacturer must make it available.

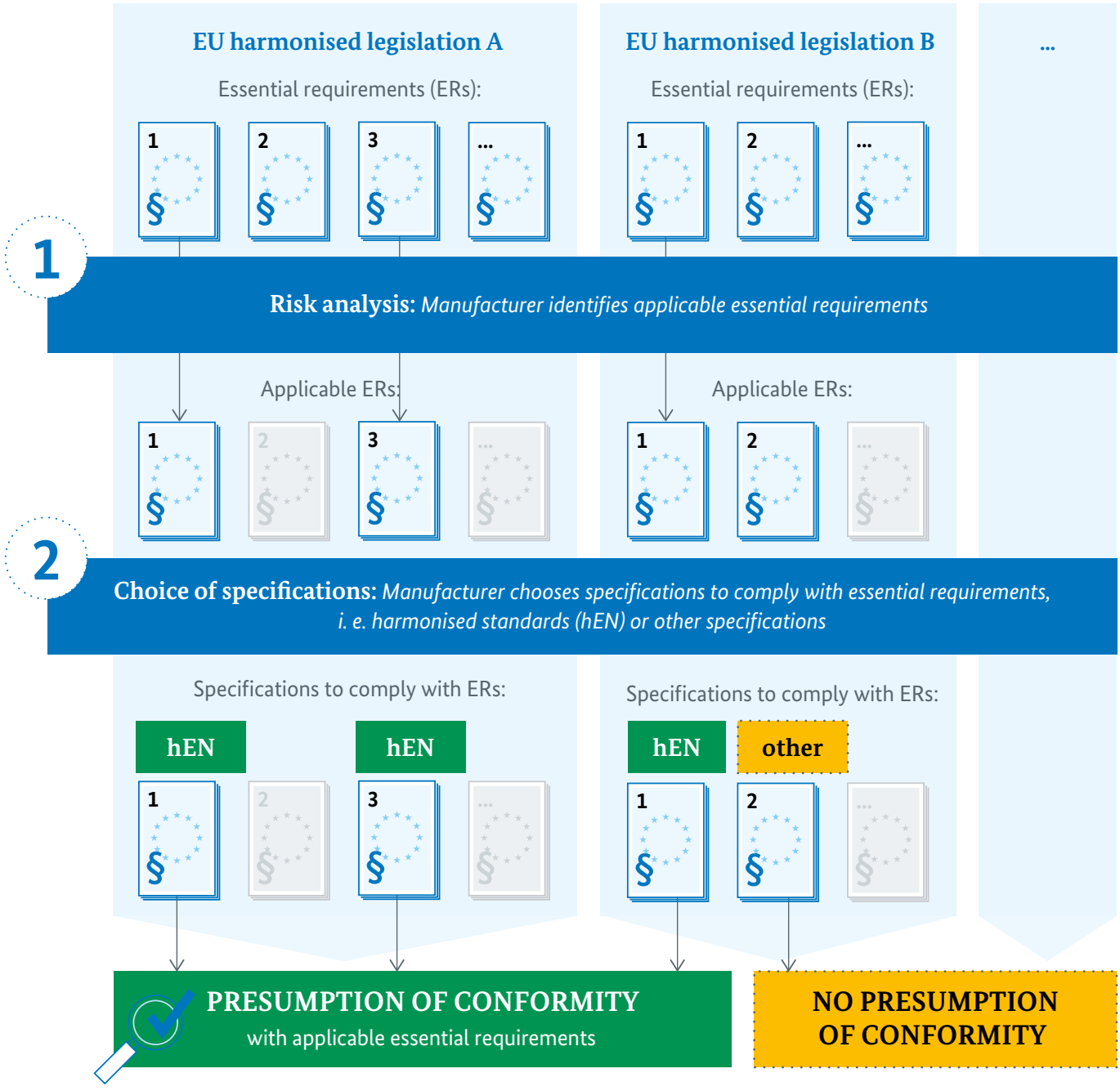
As part of the technical documentation, manufacturers must analyse a product's risk by identifying any possible hazards the product might pose. This might include, for example, whether product users could get an electrical shock or a child could choke on small parts. The manufacturer then determines which essential requirements from relevant EU harmonisation legislation are applicable based on these potential hazards. Manufacturers are then required to outline in the technical documentation how they have ensured compliance with these requirements, for example by using harmonised standards.

Benefit of using harmonised standards: presumption of conformity

If a manufacturer uses harmonised standards that are listed in the Official Journal of the EU (OJEU), the product benefits from a presumption of conformity with the essential requirements covered by such harmonised standards (see Figure 2). The presumption of conformity reverses the burden of proof: if manufacturers use these harmonised standards, then market surveillance authorities will

need evidence that a product does not comply with essential requirements. However, the presumption of conformity does not reduce the manufacturer's liability (see information box 5 above). It is also important to note that a harmonised standard may only cover some of the essential requirements. Accordingly, the presumption of conformity is valid solely for those essential requirements covered by harmonised standards.

Figure 2: Use of harmonised standards and presumption of conformity



Source: Own representation based on EU 'Blue Guide' 2016.

3.4. Manufacturer's declaration of conformity

After completing the conformity assessment procedure, the manufacturer prepares a declaration of conformity. With this document, the manufacturer (or the authorised representative) declares that the product meets all relevant EU harmonisation legislation requirements and that they have carried out the correct conformity assessment procedures. Legislation mostly requires that the EU declaration of conformity accompanies the product and/or is held by an economic operator. The document must contain information such as the name and address of the manufacturer and authorised representative, the notified body (if applicable), along with information about the product and conformity assessment procedures.

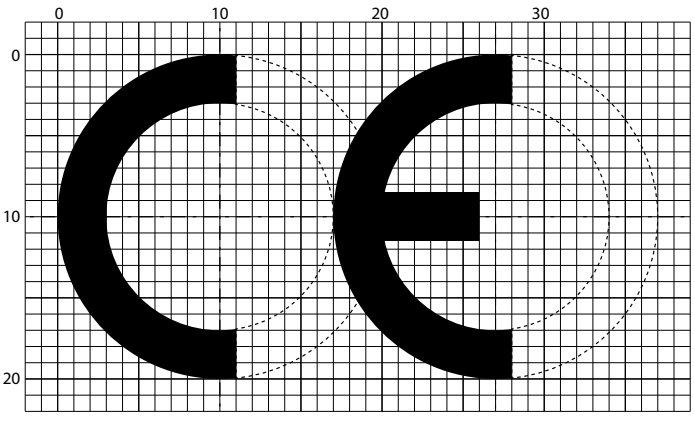
3.5. Traceability requirements

As described in Chapter 7, market surveillance authorities may order manufacturers to withdraw or recall products from the market. For this to work, authorities must be able to identify economic operators linked to a certain product. Decision No 768/2008/EC therefore mandates that products can be traced. The legislation requires manufacturers to indicate their name, registered trade mark and their contact address on the product. If this information cannot be put on the product itself, manufacturers may also provide it on the packaging or in an accompanying document.

EU harmonisation legislation does not mandate how the manufacturer should label a product to fulfil traceability requirements.[28] It is up to the manufacturer to choose, for example, whether it is printed or moulded on a product. It is in the interest of manufacturers to ensure their products are traceable throughout the supply chain, since this reduces their efforts in the event of a recall or withdrawal.[29]

3.6. CE marking

The CE marking is the visible self-declaration that a product conforms to all applicable requirements in the field of EU harmonisation legislation and that the manufacturer has successfully carried out a conformity assessment procedure.[30] CE stands for *Communauté Européenne* – French for "European Community", a predecessor organisation of the EU. Sometimes the 'CE' is also referred to *Conformité Européenne* – French for "European conformity".[31]



28 Please note that certain labelling requirements may exist in other sectors, such as chemicals.

29 Blue Guide, p. 52.

30 As indicated earlier, there is also legislation that is harmonised across the EU but is not aligned to the NLF or New Approach principles. Accordingly, the CE marking is only applicable to EU harmonisation legislation in line with the NLF and New Approach.

31 For example on the CENELEC website: https://www.cenelec.eu/faq/faq_entry.htm.

The CE marking is affixed by the manufacturer (or the authorised representative). It is only allowed to be used if harmonised legislation requires it. The marking shall be used for products placed on the EU single market, no matter where they were manufactured or where they originated.

The CE marking serves primarily as information for the relevant market surveillance authorities. It can be seen as a 'passport' for products falling under EU harmonisation legislation: the CE marking allows free movement of products into and on the EU single market. Products bearing the CE marking may only be restricted if there is evidence to prove their non-compliance. However, if a product in the area of EU harmonisation legislation does not carry the CE marking, market surveillance authorities will assume that it may endanger public interests. If a product without a CE marking is found to nevertheless meet the essential requirements, market surveillance authorities will treat it as a formal infringement and require the manufacturer to take corrective action. When market surveillance authorities find that a product that carries a CE marking is non-compliant and poses a risk to public interests, they implement follow-up measures in line with the relevant legislation (e.g. requesting the manufacturer to bring the product into compliance or initiate product withdrawals). See Chapter 7 for details on market surveillance.

Information box 6: Common misunderstandings about the CE marking

The 'C' does not stand for 'certified'.
'CE' stands for *Communauté Européenne*, which is French for European Community. Sometimes 'CE' is also referred to as *Conformité Européenne*, French for European conformity.

The CE marking does not mean that a product has been checked by an official authority.
The CE marking is affixed by the manufacturer and is a self-declaration of conformity. Legislation does not always require third-party conformity assessment.

The CE marking is not aimed at the consumer.
It works like a product passport and is intended for market surveillance authorities, not for consumers.

The CE marking is not mandatory for all products on the EU market.
Only products which fall within the scope of one or more pieces of EU harmonisation legislation must carry the CE marking. The CE marking must not be affixed to products that do not require it.

A product with the CE marking has not necessarily been manufactured within the EU.
The CE marking is only a declaration that the product fulfils essential requirements according to EU harmonisation legislation. It does not indicate the product's origin.

The CE marking is the most relevant legal conformity marking in the area of full EU harmonisation legislation (i.e. where diverging national legislation is not allowed). The CE marking can require stricter rules under sectoral EU harmonisation legislation than under the 'general' legal acts.[32] On occasions, a conformity marking other than the CE marking is to be used in accordance with sectoral harmonised legislation.[33] Member States prohibit the use of any other conformity marking that has the same meaning.

3.7. Notified bodies

Notified bodies are third-party conformity assessment bodies designated by EU Member States and notified to the European Commission. Whenever EU harmonisation legislation requires that a third-party is involved during conformity assessment, this needs to be a notified body.

A notified body must be established as a legal entity in one of the EU Member States. As they are involved in areas of public interest, this ensures that they fall under the jurisdiction of the respective Member State. However, notified bodies can also provide their services from outside the EU. This means, for example, that a notified body can use the testing laboratories of a foreign subsidiary – but the notified body registered in the EU is still legally responsible.

Decision No 768/2008/EC lays down the responsibilities and requirements of notified bodies. They must:

- be **independent** from the organisation they assess;
- be **capable** of carrying out the conformity assessment required (e.g. employ personnel with sufficient knowledge);
- be **impartial** (e.g. payment of the body's staff must not depend on the number of assessments carried out or the results of the assessment);
- be fully **responsible** for tasks carried out by their **subsidiaries** or **subcontractors**;
- have adequate **insurance** (e.g. liability insurance);
- ensure the **confidentiality of information** they obtain during conformity assessment;
- **share information** with the relevant notifying authority, market surveillance authorities and other notified bodies.

An in-house accredited laboratory cannot be a notified body.

Each notified body has a unique number. If conformity assessment involves a notified body, this number accompanies the CE marking (see example on the right).

CE 0589

Example of CE marking with the number of the involved notified body (here the German Federal Institute for Materials Research and Testing, BAM)

32 For example under the 'Construction Products Legislation'.

33 For example, the EU energy label for energy-related products. Regulation (EC) No 552/2004 on the interoperability of the European Air Traffic Management network does not provide for CE marking.

Procedure for Member States appointing notified bodies

Member States appoint notified bodies and must notify them to the European Commission. National authorities must verify that a conformity assessment body seeking notification is competent in line with the requirements set out in the relevant EU harmonisation legislation. Accreditation based on the EN ISO/IEC 17000 series of standards is the preferred approach to evaluating the technical competence of conformity assessment bodies. The New Legislative Framework does not require notified bodies to be accredited. However, Member States can make accreditation mandatory when transposing EU legislation into national legislation. Furthermore, if national authorities choose a body which is *not* accredited, they must supply evidence to the European Commission and Member States verifying a body's technical competence.

A conformity assessment body seeking notification should send an application to the responsible notifying authority of the Member State in which they are located. The national authority then verifies the evidence of the competence in line with the applicable legislation. If the conformity assessment body fulfils the requirements, the national authority will inform the European Commission and the Member States that the body concerned may carry out conformity assessment in line with the relevant EU harmonisation legislation. Provided there are no objections from the European Commission or the Member States, the notification is published on the website of the New Approach Notified and Designated Organisations (NANDO) information system. It thereby takes effect. The national authority is required to continuously monitor the notified body to ensure it meets the relevant requirements – information published in NANDO must be updated every five years at least. Please refer to Figure 3 for an overview of the notification procedure.

National authorities appoint notified bodies

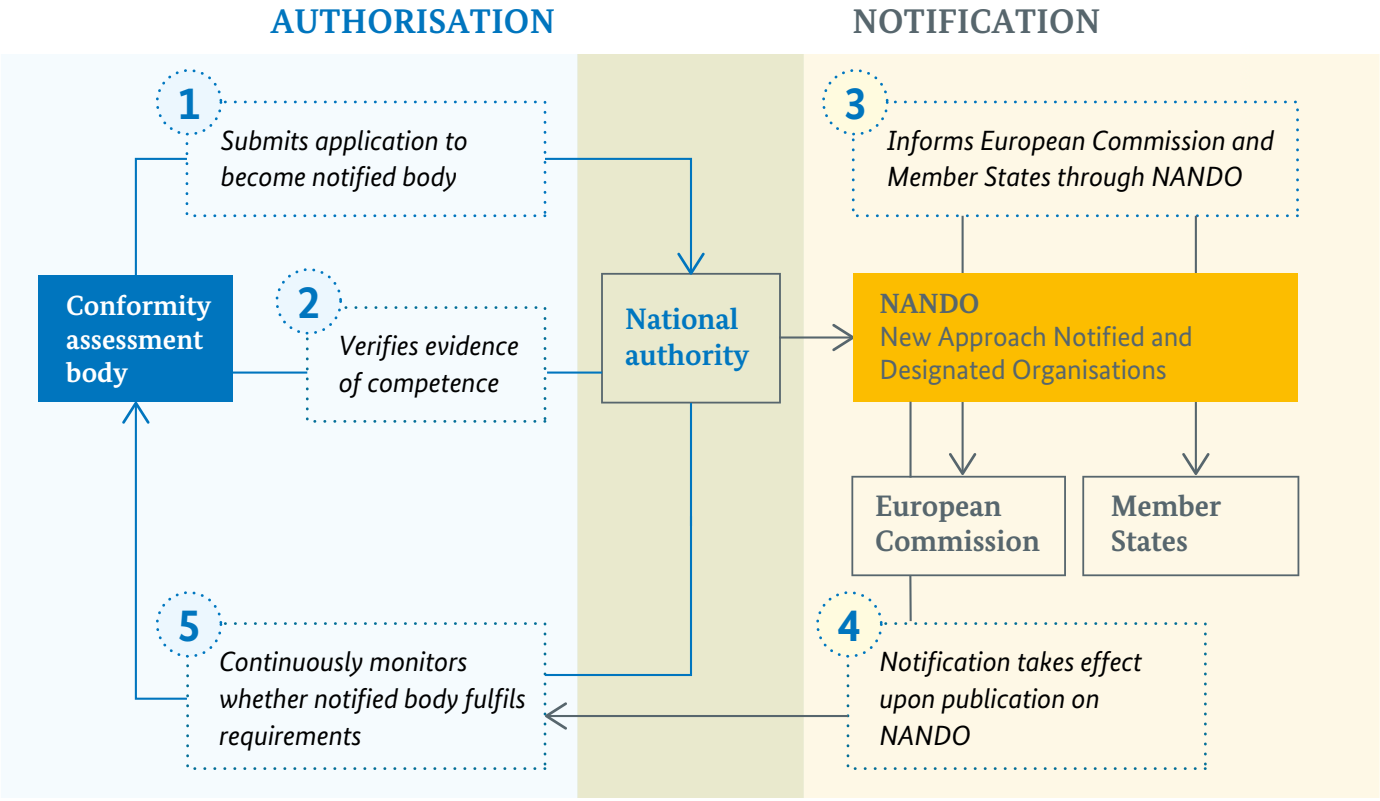
Member States choose the notifying authorities which assess, notify and monitor notified bodies. These authorities are responsible for checking the competence of the bodies they notify – even if these are accredited. Notifying authorities must not have a conflict of interest with conformity assessment bodies, nor are they allowed to offer any conformity assessment services themselves which may be in competition with those of conformity assessment bodies.

In Germany, there are thirteen notifying authorities. These are mainly federal or state ministries and federal authorities:

- Bavarian State Ministry for Housing, Building and Transport
- Federal Office for Goods Transport (BAG)
- Federal Maritime and Hydrographic Agency
- Federal Supervisory Authority for Air Navigation Services (BAF)
- Federal Ministry of the Interior, Building and Community (BMI)
- Federal Ministry for Economic Affairs and Energy (BMWi)
- Federal Network Agency for Electricity, Gas, Telecommunications Post and Railway (BNetzA)
- German Institute for Construction Engineering (DIBt)
- Federal Railway Authority (EBA)
- Federal Office for Agriculture and Food (BLE)

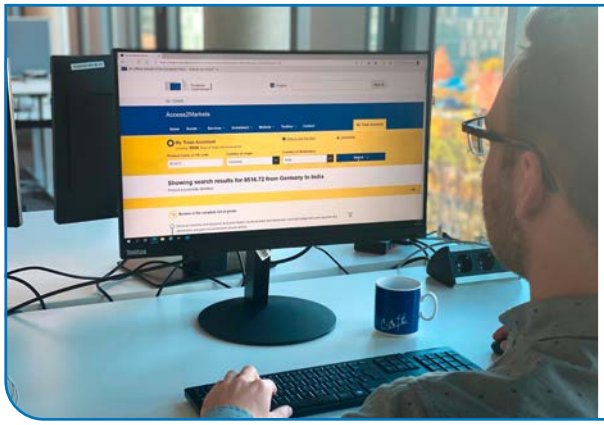
- Federal Aviation Office
- Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG)
- Central Authority of the Federal States for Safety Engineering (ZLS)

Figure 3: Process of notifying conformity assessment bodies

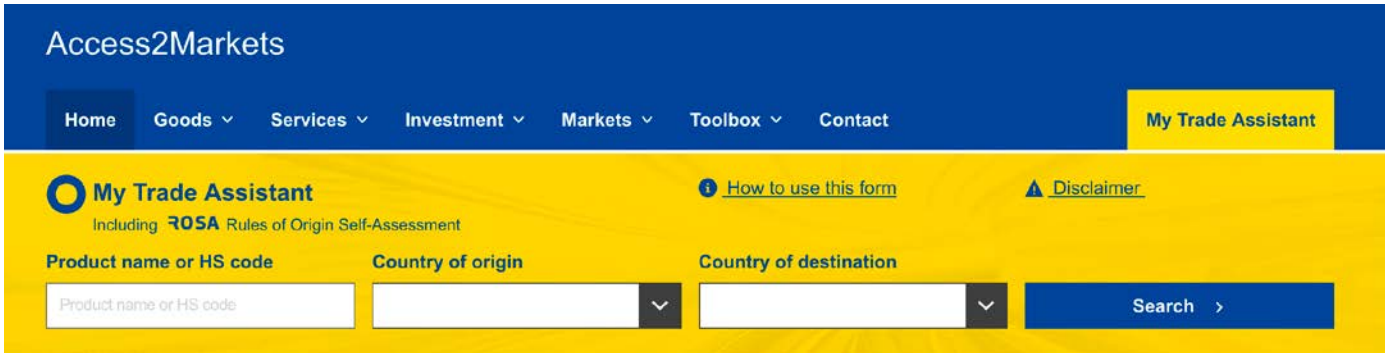


Source: Own representation.

Information box 7: The EU Trade Helpdesk



Companies seeking to export to or import from the EU can find detailed information at *Access2Markets* (available at https://trade.ec.europa.eu/access-to-markets/). This free online portal includes information on trade agreements, customs procedures and formalities, tariffs and taxes, trade barriers, rules of origin and trade flow statistics. Companies can search by product, country of origin and country of destination.



Case studies: As a manufacturer, how do I demonstrate that my product complies with EU legislation?

For our two product case studies, we focus on compliance with EU harmonisation legislation leading to CE marking. Manufacturers must complete the following steps:

1. identify applicable legislation (and harmonised standards → see next chapter);
2. check the product-specific requirements;
3. identify which conformity assessment is required;
4. carry out the conformity assessment (possibly with the involvement of a notified body);
5. draw up the technical documentation and keep copies;
6. affix the CE marking and issue the EU declaration of conformity;
7. ensure fulfilment of other formal requirements.

Toaster

Let's have a look at what these steps look like for our toaster:

1. **Applicable legislation:** In the previous chapter we identified which legislation must be fulfilled before the CE marking can be affixed to our toaster: the Electromagnetic Compatibility (EMC) Directive 2014/30/EU, Low Voltage Directive (LVD) 2014/35/EU and the Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU.

2. **Check product-specific requirements:** It is the responsibility of the manufacturer to check whether the toaster meets the specific legislative requirements. For example, Annex I of the LVD formulates the following essential requirements:

   "Measures of a technical nature shall be laid down (...) to ensure that: a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact; and b) temperatures (...) which would cause a danger are not produced."

→

Not all requirements in these three directives necessarily apply to the toaster. So the manufacturer must first assess any risks the toaster may pose: hazards such as electric shocks, a rise in temperature of the toaster's outer casing, a failure of the mechanism to eject the toast or sharp edges. This risk analysis determines the essential requirements the toaster must meet. Manufacturers can then freely decide how to meet these requirements. They can use harmonised standards, but may also choose other technical specifications (see information on harmonised standards in the next chapter).

3. **Conformity assessment procedure (e.g. need for involving a notified body):** It is the responsibility of the manufacturer to assess the toaster's conformity with the essential requirements applicable. The legislation defines which conformity assessment modules manufacturers must use or from which they can choose. This also determines whether or not they will need to involve a notified body:

   a. **EMC directive:** Manufacturers can choose between conformity assessment through internal production control (Module A) or a combination of EU type examination (Module B) and conformity to type (Module C). They may involve a notified body if they select the second approach, i. e. a combination of Modules B and C. This is a voluntary decision of the manufacturer which takes into account aspects such as the complexity of the product, standards used and the manufacturer's capacity for internal production control.

   b. **LVD and RoHS directives:** These directives do not mandate the involvement of a notified body. They only require conformity assessment based on internal production control (Module A).

   If a manufacturer chooses to involve a notified body during conformity assessment of their toaster in line with the EMC directive, a list of notified bodies can be found on the Nando (New Approach Notified and Designated Organisations) Information System. There are 113 notified bodies approved for the EMC directive – 10 of these are based in Germany.

4. **Carry out conformity assessment:** The manufacturer carries out conformity assessment to check its conformity, possibly with the involvement of a notified body (for EMC).

5. **Technical documentation:** As part of the conformity assessment, the manufacturer is required to draw up technical documentation – in this the manufacturer must also document the risk analysis that identified the legislation applicable and essential requirements. The New Legislative Framework harmonised the content required in the technical documentation. For aligned legislation such as the EMC and Low Voltage directives, technical documentation for internal production control comprises the following parts.

→

a. General description of the electrical equipment.
b. Conceptual design and manufacturing drawings and schemes of components etc.
c. Descriptions and explanations necessary to understand these drawings and schemes and to operate the electrical equipment.
d. A list of harmonised standards applied in full or in part by the manufacturer. Where they have not been applied, the manufacturer must describe any technical solutions adopted to meet legislative requirements.
e. Results of design calculations made, examinations carried out, etc.
f. Test reports.

6. **CE marking:** The manufacturer can then affix the CE marking to the toaster and issue the EU declaration of conformity. As for all products, the CE marking must be affixed to the toaster in a clearly visible and legible manner. The size of the marking can be adapted, but its proportions must remain as defined by the EU.

7. **Fulfilment of other formal requirements:** Before the toaster can be placed on the market, the manufacturer must comply with certain other administrative requirements. For market surveillance authorities to be able to trace the product and the economic operator, manufacturers must affix to the toaster information such as the name and address of the manufacturer – and, where applicable, of the European importer – as well as an element that enables identification of the toaster (e.g. type and batch number).[34] In addition, the toaster must be accompanied by instructions for its intended use. These instructions must be prepared in a language easily understandable by the end user – in Germany, they must be in German.

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34 If it is not possible to affix this to the toaster, it can also be shown on packaging or an accompanying document.

Electric motor

Due to the alignment of legislation to the provisions of the New Legislative Framework, the steps for the electric motor are almost identical to those for the toaster:

1. **Applicable legislation:** Electromagnetic Compatibility (EMC) Directive 2014/30/EU, Low Voltage Directive (LVD) 2014/35/EU, Regulation (EC) No 640/2009 (replaced by Regulation (EU) 2019/1781 from July 2021).

2. **Check product-specific requirements:** It is the responsibility of the manufacturer to check whether the electric motor meets specific legislative requirements. By carrying out a risk analysis, the manufacturer assesses any risks the electric motor may pose: electric shock, mechanical failure due to overload, overheating, sharp edges, etc. This risk analysis determines which essential requirements the motor must meet.

3. **Conformity assessment procedure (e.g. need for involving a notified body):** For the electric motor, the legislation does not mandate the involvement of a notified body – but the manufacturer may of course voluntarily involve a third-party conformity assessment body. For the EMC, LVD, and RoHS directives, the choice of conformity assessment modules is the same as for the toaster.

   With regard to the Ecodesign regulation for electric motors, the manufacturer can either conduct an internal design control or use a management system for assessing conformance. The regulation does not mandate the involvement of a notified body.

4. **Conformity assessment:** The manufacturer carries out conformity assessment and checks its conformity, possibly with the involvement of a notified body (for EMC).

5. **Technical documentation:** The manufacturer draws up technical documentation in the same way as described above.

6. **CE marking:** The manufacturer affixes the CE marking to the electric motor and issues the EU declaration of conformity.

7. **Fulfilment of other formal requirements:** As with the toaster, the electric motor must comply with additional administrative requirements, including those relating to traceability and accompanying instructions (see page 54).

4. Standardisation

Driven by industry and recognising the primacy of international standards, voluntary standardisation benefits both business and society

Key points in this chapter

- Standards can be used voluntarily. They are developed by stakeholders – particularly those in the private sector – who see a relevance and market need for them.
- Development of standards follows the principles of consensus, openness, transparency, coherence and non-discrimination.
- The German standardisation organisations DIN and DKE act by 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.
- Although voluntary, harmonised European standards are tools that support EU legislation.

4.1. Overview of standardisation in Germany and Europe

Standards are developed by those who see a relevance and market need for them

Voluntary and consensus-based standards are beneficial to the public sector, businesses, and society. They support self-regulation by the industry and the government in regulation.[35] By improving product safety and quality, standards build trust between market participants and reduce transaction costs. International standards lower barriers to trade and help businesses create or enter new markets.

Standardisation was estimated to generate an annual national economic benefit in Germany of about 17 billion euros – constituting approx. 0.7 percent of Germany's gross domestic product (GDP).[36] Standards support the spread of best practices and state-of-the-art procedures. Companies can build on the latest technologies and approaches and develop them further – this creates innovation. The positive economic effect of standardisation also goes beyond this knowledge spillover: for example, standards reduce the number of workplace accidents and increase overall quality of life. Such secondary effects are difficult to measure but contribute in a major way to economic and social progress.[37]

35 The following sections made use of material from the publication "An introduction to standardization" (2016) edited by DIN, the Association of German Chambers of Industry and Commerce (DIHK), and the German Confederation of Skilled Crafts (ZDH). Please find this publication also referred to in Chapter 8 "Further Reading".

36 Blind et Al., 2011, The Economic Benefits of Standardization, issued by DIN. Available at https://www.din.de/blob/89552/68849fab0eeeaafb56c5a3ffee9959c5/economic-benefits-of-standardization-en-data.pdf.

37 ibid.

"Those who comply with standards ensure quality. Standards help to build confidence in new technologies, reduce costs, promote international trade and protect both people and the environment. We believe that the digitalisation of quality infrastructures creates further opportunities to ensure quality, even across borders."

Christoph Winterhalter,
Chairman of the Executive Board, DIN

The application of standards offers many advantages for companies. Standards enjoy broad acceptance, since they build on the latest approaches and technologies accepted by leading experts. Standards ensure that things fit, that they are compatible, interoperable and comparable. These are key factors for a company's success in value chains. Standards also help companies to meet market expectations and follow legal requirements – particularly when laws simply define essential requirements.

Companies – both big and small – as well as testing laboratories and researchers gain from contributing to standards development themselves. They join a network of leading experts in their field and are the first to know about important market trends. Companies that are involved in standards development can promote their own solutions. This gives them a competitive advantage: they can impact the standard setting.

Given these benefits of using and developing standards, the private sector is actively involved in standardisation across Germany, Europe and internationally. Standardisation is a voluntary, consensus-based and strongly market-driven activity. Standards are developed by those who see a relevance and market need for them.

Good standards – a matter of principles

The German Institute for Standardization (*Deutsches Institut für Normung*, DIN) and the German Commission for Electrical, Electronic & Information Technologies of DIN and VDE (*Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE*, DKE) are the recognised national standards bodies in Germany. In 1975, DIN entered a public-private partnership with the Federal Republic of Germany by signing the Standards Agreement in which DIN is acknowledged as the national standards body in Germany. Its task as an independent platform is to coordinate standards development in Germany and also represent public interests.

As the platform for standardisation in Germany, DIN and DKE ensure that standards development follows important principles (see Table 2 for a list of principles). These include that participation in standards development and their use are entirely voluntary. The development process must be open to all interested parties and the public should be able to propose new work items and comment on draft standards. The drafting of standards follows a consensus-based approach and the comments of all interested parties must be considered before a draft standard can be adopted. Germany puts international standardisation first: standards shall support the reduction of technical barriers to trade and – wherever possible – preference is given to international standardisation. By following these principles, Germany embraces the World Trade Organization's (WTO) Code of Good Practice for the Preparation, Adoption and Application of Standards (see information box 6).

Table 2: Principles of standards development at DIN and DKE[38]

Principle	Description
Voluntary nature	Participation in standards work and the use of standards (in most cases) are voluntary.
Openness	All standards proposals and draft standards are made public for comments before the final version is published. Those having comments or objections are asked to join in the negotiations, and every objection is to be discussed with the person making it.
Broad participation	DIN Standards are developed in Working Committees by external experts representing all stakeholders. Anyone can participate in this process. Arbitration procedures secure the rights of minority interests.
Consensus	The principles of standards work at DIN and DKE ensure fair procedures for all interested parties, the core aspect of which is guaranteeing a balanced consideration of all interests during the consensus-building process. The content of standards is thus laid down on the basis of mutual understanding and general agreement.
Uniformity and consistency	The collection of DIN Standards covers all technical disciplines. The rules of procedure in standards work ensure the uniformity and consistency of these standards.
Technical relevance	DIN Standards mirror reality. By definition, a technical standard must take general wellbeing into consideration and reflects not only what is technically possible, but also what is generally acceptable.
State of the art	Standardisation takes account of current scientific knowledge and ensures the rapid implementation of new findings. DIN Standards document the current state of the art.
Market relevance	A standard is developed only where it is absolutely necessary, because standardization is not an end in itself.
Beneficial for society	DIN Standards always take the needs of society as a whole into consideration. The benefits to the general public take priority over the benefits of individuals.
International relevance	Standards work at DIN helps eliminate technical barriers to free global trade and within the European Single Market. This requires international and European Standards.
Compliance with antitrust legislation	DIN's statutes and rules of procedure ensure that our work is in full compliance with all relevant antitrust laws.
High acceptance	Because all stakeholders are involved in their development, and because they are developed in consensus, DIN Standards are not only accepted by industry and the state but also by consumers.
Democratic legitimation	The consensus process with its public commenting, mediation and arbitration procedures lends a democratic legitimation to DIN's work results that is highly valued by users, especially in terms of consumer protection, environmental protection and occupational health and safety.
Delegation	DIN and DKE on behalf of the Federal Republic of Germany delegate German experts to represent the national interests within corresponding European and international standardisation organisations.

38 The table is based on information provided on the official DIN website and available at https://www.din.de/en/about-standards/din-standards/principles-of-standards-work.

Information box 8: Code of Good Practices for Standards Development of the World Trade Organization (WTO)

- **equal treatment of products** of national and foreign origin;
- national standards shall **not create unnecessary obstacles to international trade**;
- preference to **international standards**;
- **participation** of national delegations in **international standardisation**;
- **avoiding duplication or overlapping standardisation work** (both nationally, and internationally);
- focus on **performance requirements** rather than design or descriptive characteristics;
- publication of a **work programme** of standardisation activities;
- **public consultations** before adoption of a standard;
- **equal treatment of comments** on draft standards.

Summary of key points of the "Code of Good Practice for the Preparation, Adoption and Application of Standards" in Annex 3 of the WTO Agreement on Technical Barriers to Trade. Available at https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.

Standards vs specifications: a trade-off between principles and speed

Recognising the importance of such principles, the German language distinguishes between standards (German: *Norm*) and specifications (German: *Standard*). From the German point of view, standards (or Norm in German) can only be called standards if they were developed through broad involvement of all interested parties, were made available for review and commenting in a public enquiry, and implement decisions made in consensus. In contrast to such standards, a DIN and VDE Specification does not require full consensus and the involvement of all stakeholders; this document is called a *Standard* in German language. DIN and DKE elaborate standards based on full consensus and broad stakeholder involvement. However, in common with other organisations such as industry associations, fora and consortia, DIN and DKE also develop specifications in order to meet timely market needs (see page 67).

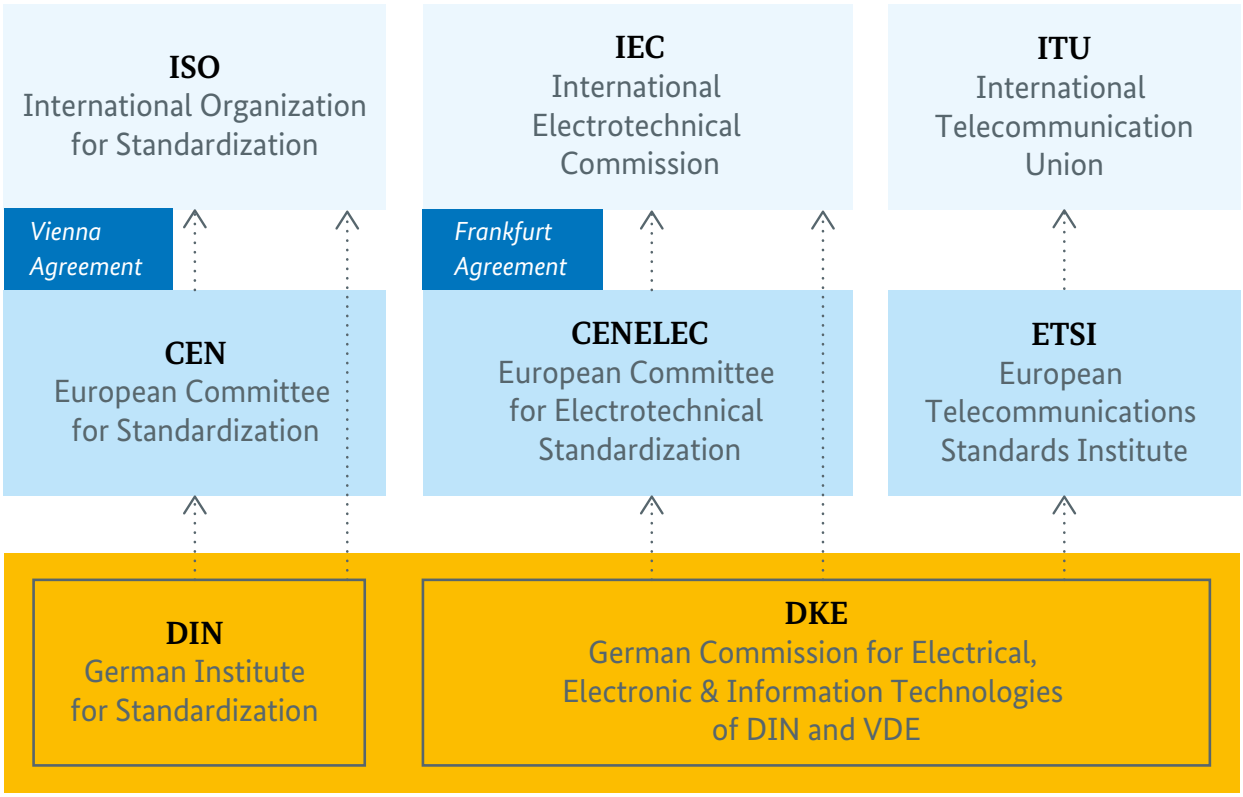
German standardisation is embedded at the European and international level

German standardisation has a consistent international agenda.[39] Standards provide a common technical language for trade partners throughout the world and ease value chains that cross borders. Drafting standards at the international level also reduces workload. Resources are used more efficiently when experts share their knowledge at the international level.

Germany's standardisation system is therefore embedded in the European and international systems.

With regards to the development of European standards for products in support of EU product legislation, established rules for the cooperation between European standardisation organisations, national standardisation bodies, Member States, and the European Commission are laid out in Regulation (EU) No 1025/2012 on European standardisation. This cooperation is coordinated in the EU comitology Committee on Standards chaired by the European Commission where German standardisation interests are represented and protected by the German Federal Ministry for Economic Affairs and Energy on behalf of Germany.

Figure 4: Relationship between German, European and international standards bodies



Source: DIN and DKE.

39 As stated in the German Standardization Strategy in 2016, https://www.din.de/resource/blob/235256/ac5667b8524c331684222d7a2ac47ab4/the-german-standardization-strategy-data.pdf.

When it comes to the standardisation work in the privately organised standardisation bodies, German experts contribute actively to international standardisation and thereby support technological progress globally. Around 85 percent of standardisation projects at DIN are of European or international origin. In the field of electrotechnical standards, for example, a mere 5 percent of them are German standards that are not based on European or international standards.

Institutionally, DIN and DKE are intricately linked to their European and international partners. DIN represents Germany's interests at the European Committee for Standardization (CEN) and the International Organization for Standardisation (ISO). DKE represents Germany at the European Committee for Electrotechnical Standardization (CENELEC) and the International Electrotechnical Commission (IEC). All these national delegations on the European and international level take part on behalf of the Federal Republic of Germany. However, the German government does not give specific directions. Germany's standpoints are rather discussed at the most in strategic collaborative working groups between the government and the standardisation organisations and they are decided in national mirror committees of the national standards bodies. In the context of their international work, DIN and DKE are tasked with monitoring the developments of ISO and IEC, CEN and CENELEC in their respective national mirror committees. They decide on the national position with regard to the respective topics and projects. The mirror committees then send national delegations to represent the national position and to contribute to the work at European and international level (see Figure 4).

"DKE's activities in international electrotechnical standardisation are evidence of our active support for quality infrastructure. We stand for a safe, sustainable, digital world and contribute to enabling free trade. Our motto: Do it once, do it right, do it internationally!"

Florian Spiteller, Head of External Relations & Support, Member of the DKE Executive Board, DKE

Vienna and Frankfurt Agreements: Europe's commitment to international standards

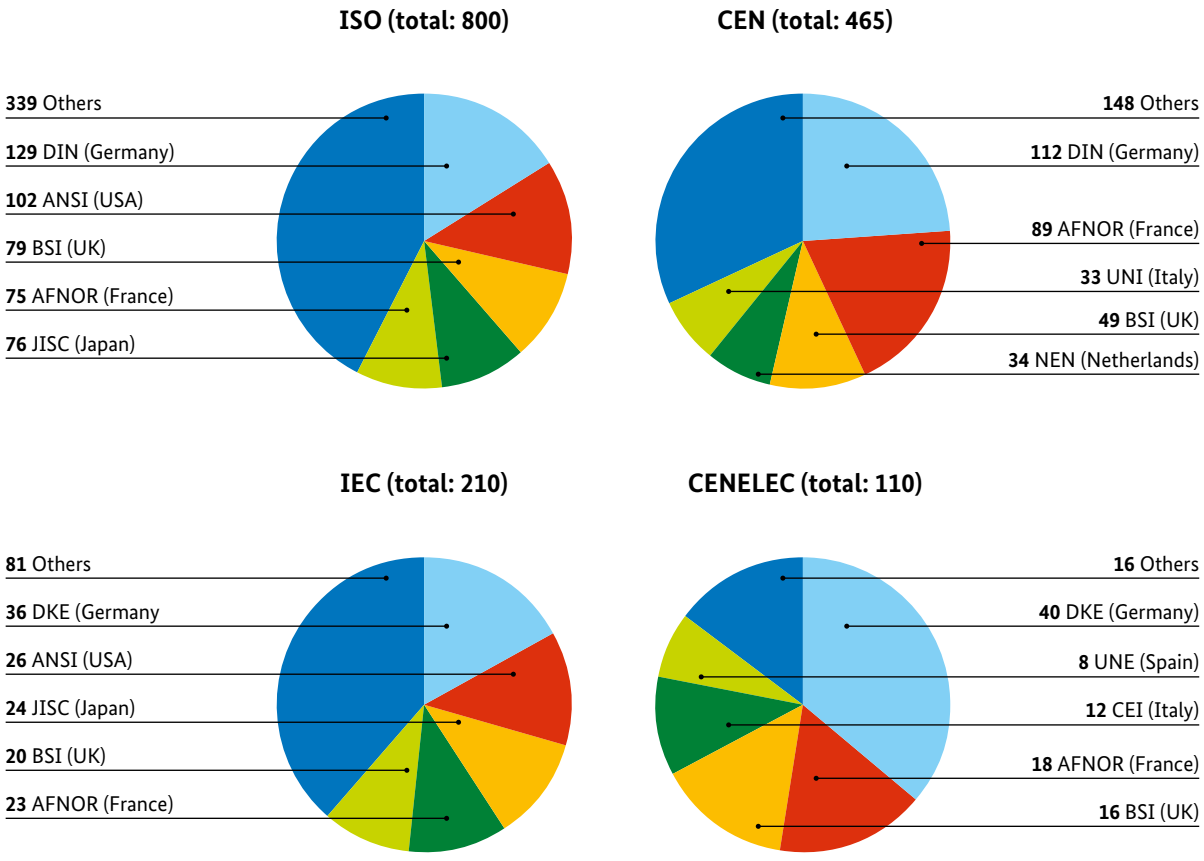
Agreements between the European and international standardisation organisations ensure the primacy of international standards in Europe – and are an important pillar of international standardisation in general. By signing the Vienna Agreement in 1991, CEN and ISO agreed to jointly plan new standards projects and share information. The two organisations collaborate closely and thereby save resources and time in standards development. A standard can be developed either under the lead of ISO or CEN and can be simultaneously approved as both an European and an international standard. Whenever possible, standards are developed at the international level. All CEN members must adopt European standards, unchanged, as national standards – and withdraw any conflicting national standards. This means that all CEN and CENELEC members apply the same European standards. This is one of the foundations of the European single market.

The Vienna Agreement is the most far-reaching agreement between ISO and any regional standards body and an example of how to realise the primacy of international standards. However, the agreement also acknowledges that CEN might choose to develop a European standard rather than an inter-

national standard. This might be the case if there is no recognised need at the international level or if the European market urgently requires a standard.

In the electrotechnical field, CENELEC and IEC signed a similar cooperation agreement in 1996 (Dresden Agreement), which was updated in 2016 (Frankfurt Agreement). The agreement has three main principles: parallel voting on draft international standards, common planning, and offering of new work. The aim is to increase transparency and to ensure the best use of resources available for standardisation. This means that all IEC standards are automatically voted in parallel at CENELEC level. If CENELEC starts a new standardisation project, it will be offered to IEC. If IEC has an interest in the proposed item, the work will be transferred to IEC. If IEC does not take it up, CENELEC will continue the work on the standard and keep IEC informed. If a CENELEC standard is published, it will be offered to IEC for adoption. As a consequence of this agreement, around about 85 percent of European standards are similar or based on IEC standards.[40]

Figure 5: Number of secretariats of technical committees (TCs) and subcommittees (SCs) held by national standards bodies (as of June 2020)



Source: Data from CEN/CENELEC, ISO and IEC.

40 See https://boss.cenelec.eu/fadel/Pages/default.aspx.

4.2. Landscape of standardisation in Germany

Public-private cooperation sets the framework for self-governance in standardisation

In Germany, standardisation is principally a responsibility of the private sector. The German Federal Government, through the German Federal Ministry for Economic Affairs and Energy (*Bundesministerium für Wirtschaft und Energie*, BMWi), established the framework for standardisation. Standards work itself is organised by DIN, which is a private non-profit association. It is not a public authority, however representing public interests. To standards development the public sector may contribute as an interested party, just like any other stakeholder.

In 1975, DIN and the Federal Republic of Germany signed a public-private partnership agreement which laid down DIN as the national standards body, and thereby also covers DKE. The contract obliges DIN and DKE to consider the public interest in their standardisation work and follow fair procedures that also enable the participation of weaker economic stakeholders (e.g. small and medium-sized enterprises, SMEs). The agreement foresees also the use of standards as references in legislation which define technical requirements. The German Government recognises that DIN and DKE, as the national standards bodies, represent Germany internationally. The agreement also requires the German Government to apply DIN standards to administrative procedures and tenders as applicable and to ensure that other public authorities do the same.[41] The agreement further defines the cooperation between DIN and the German Federal Government being implemented on different levels.

DIN as an independent platform for standardisation

As a private organisation and registered non-profit association, DIN's work is primarily financed through the sale of standards and related services (63 percent of revenue in 2019). Membership fees (10 percent) and project funds from the industry (19 percent) are further revenue sources. Project funds from the government account for only 9 percent (see Figure 6 below). This funding structure guarantees that standardisation follows the needs of the market: standards are developed only if interested parties require them. When evaluating new proposals for standards, DIN liaises with the relevant experts to consider the need for a standard on that subject, to discuss if they are willing to finance the project, and whether the work is to be carried out at national, European or international level. This provides a clear indicator that a standard is relevant and serves a market need.

DIN's network includes more than 35,500 experts representing industry, research, consumer protection and the public sector who bring their expertise to standardisation. In over 3,600 committees they develop around 2,000 new standards every year.[42]

DKE – Building on VDE's long-standing experience in electrotechnical standardisation

Electrotechnical standardisation takes place at DKE. DKE is a division of the Association for Electrical, Electronic & Information Technologies (*Verband der Elektrotechnik Elektronik Informationstechnik*, VDE). Founded in 1893, VDE is one of Europe's oldest and largest technical-scientific associations which has been developing standards since the end of the nineteenth century.

41 See https://www.din.de/resource/blob/79650/76ad884fb2c4dd6aa5b900e7a1574da6/contract-din-and-brd-data.pdf.

42 In 2017, 1,959 new standards were developed at DIN (source: official data from DIN).

In 1970, VDE and DIN jointly formed DKE as the German standardisation body for electrical engineering, electronics, and information technology. DKE is covered by the standards contract between the Federal Republic of Germany and DIN. Standards developed by DKE are published as DIN standards. If they are related to safety, they carry a VDE classification: e.g. DIN VDE 0100:2019 Low-voltage electrical installations.

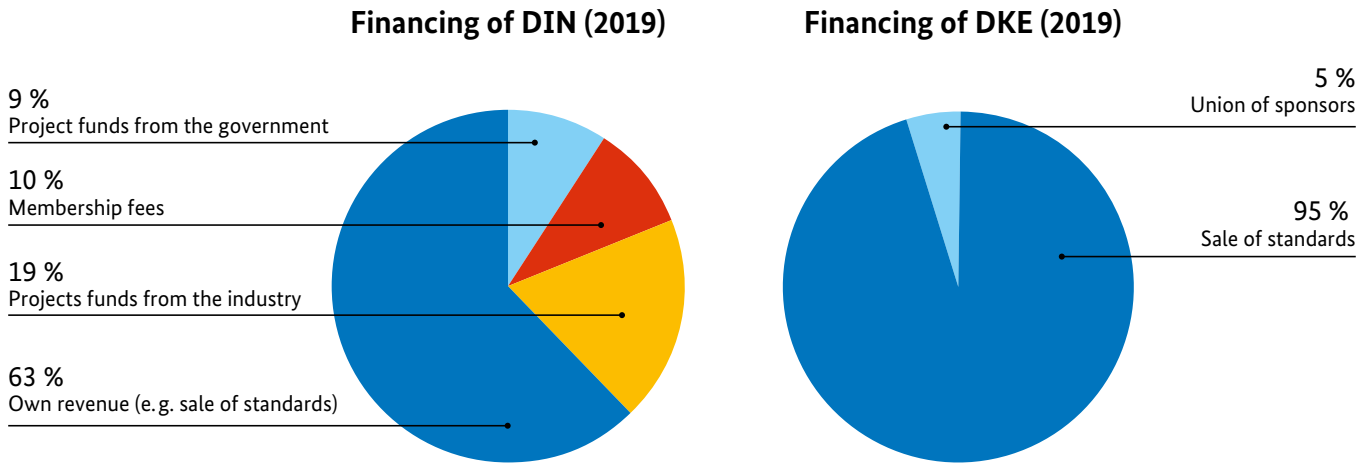
An Executive Council determines DKE's core principles with support from sector-specific advisory boards. The Executive Council comprises a broad market representation of key figures from various stakeholder groups, including industry and professional associations, as well as federal ministries, and other public representatives. The DKE network involves around 9,000 experts who work in 1,200 committees to develop around 500 standards per year.[43]

The financing of DKE does not involve any membership fees or government subsidies. About 95 percent of DKE's revenues stem from the sale of standards. A union of sponsors make up the remaining 5 percent of DKE's revenues (see Figure 5).[44]

Shape the future with standardisation! – Germany's standardisation strategy

In 2016, the latest version of the German standardisation strategy was drafted by all stakeholders involved in standardisation, including representatives from industry, consumer protection and occupational health and safety organisations, health and environmental protection groups, technical and scientific associations and the public.[45] The strategy is a living document which will be continually developed by the interested parties. It outlines six goals which serve as an orientation for

Figure 6: Revenues of DIN (left) and DKE (right) in 2019



Source: Official data from DIN and DKE.
Note: Percentages may not total 100 due to rounding.

43 Source: Official data from DKE.

44 Source: Official data from DKE.

45 The English version of the German Standardization Strategy can be accessed at https://www.din.de/en/din-and-our-partners/din-e-v/german-standardization-strategy.

standards work in Germany in the context of changing needs and new challenges:

- Goal 1: International and European trade is facilitated by standardisation.
- Goal 2: Standardisation is an instrument of deregulation.
- Goal 3: Germany is at the forefront of bringing future-oriented topics into standardisation on a worldwide scale through the networking of stakeholders and the establishment of new processes and open platforms for coordination.
- Goal 4: Industry and society are the driving forces in standardisation.
- Goal 5: Standardisation is used in particular by companies as an important strategic instrument.
- Goal 6: Standardisation is highly regarded by the public.

The strategy sets a high value on the European and international context, in particular activities within ISO and IEC. It emphasises the participation of the industry in standardisation processes, balancing the mutual interests of policymakers and standards setters, and advancing standards development for the public interest – for example by enhancing the transparency of standards processes and structures.

4.3. Process of standards development in Germany

Anyone can take part in standards development in Germany. There are no quotas for certain stakeholder groups or restrictions to membership. The principles of standardisation work in Germany are – of course – laid down in a standard: DIN 820.

The process of standards development starts with a proposal for new standards work. Anyone can send such a written request, for example through an online form on the websites of DIN and DKE. Every proposal is assessed by experts responsible at DIN and DKE. In line with DIN 820, they check in particular whether:

- there is a need for such a standard (or expected need);
- interested parties are willing to contribute to its development;
- standardisation projects are already under way in European or international standardisation organisations;
- the subject can be considered for European or international standardisation;
- the development of a standard is economical, i.e. that financing the development costs is secured.

If the proposal is accepted, a technical committee is tasked with this standard project. A new committee is formed if needed. Notifications on the DIN and DKE website inform the public about new standard projects.

All interested parties can participate in the technical committee for development of a draft standard. At DIN, committee members are required to pay a fee to cover DIN project management costs. Committee members do not need to be formal members of DIN or DKE/VDE. A draft standard is developed in consensus with all members involved.

Draft standards are then published for public commenting for a period of two to four months. Anyone can submit comments through online forms of DIN and DKE. Subsequently, the committee

Figure 7: Process of standards development in Germany (based on DIN infographic)

Source: DIN.

reviews the draft based on these comments and decides whether and how to include them. After finalisation, DIN publishes the standard and reviews it at least every five years. An overview of this process is shown in Figure 7.

If time is short: DIN SPEC and VDE SPEC

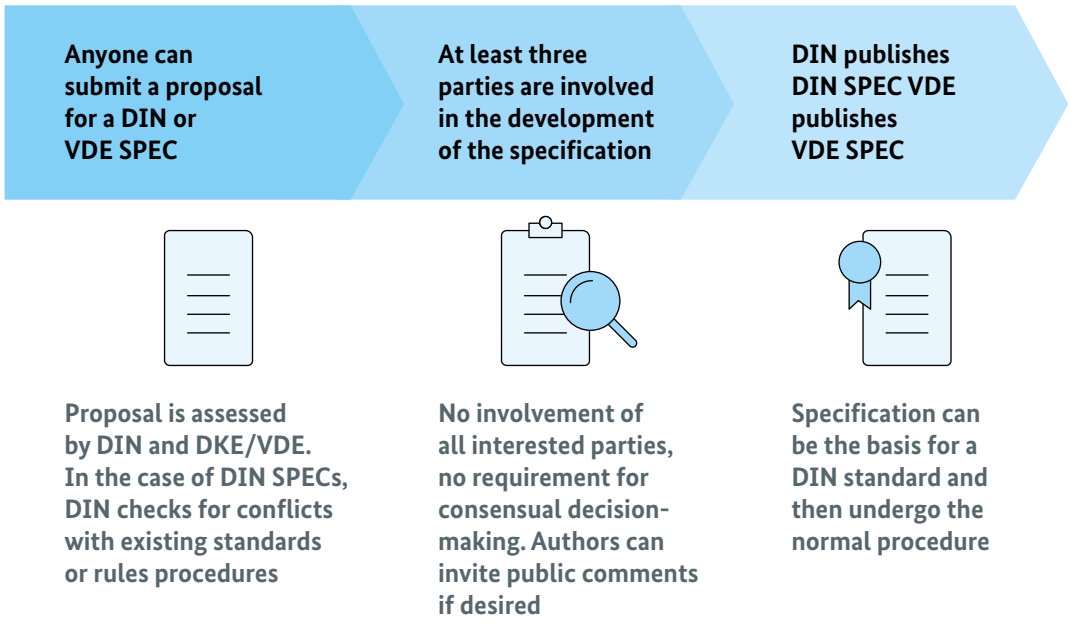
In view of the increasing speed of technological developments, DIN and DKE created specifications which can be developed faster than standards: DIN SPEC and VDE SPEC. Unlike standards developed in line with the process described above, these specifications do not require the participation or full consensus of all interested parties (see Figure 8).

Development of DIN and VDE SPECs requires at least three parties to be involved. In the case of DIN SPECs, DIN needs to ensure that there is no conflict with any existing standards or specifications. In order to stimulate discussion and accelerate standardisation, a VDE SPEC may conflict with other VDE SPECs or standards – but not with legislation, administrative provisions, or harmonised standards. The development process of DIN SPECs takes a few months, VDE SPECs a few weeks.

Standards committees in Germany: strong role of the industry

The technical work of standardisation takes place in technical committees. One committee is responsible for one particular standardisation task and also performs these tasks in collaboration with the European and international standards organisations. Technical committees can be either directly under the roof of DIN or hosted by other associations (but also under the DIN umbrella). Either way, they are all working according to DIN rules and should not be confused with independent standards development organisations (SDOs).

Figure 8: Process of developing DIN and VDE SPECs



Source: DIN.

If committees are hosted by other associations, this is usually due to a consolidated technical experience within such associations or a long-standing experience in standards development. For example, the DIN Standards Committee Mechanical Engineering (NAM) is hosted by the German Mechanical Engineering Industry Association (*Verband Deutscher Maschinen- und Anlagenbau*, VDMA). VDMA is the sponsor of this particular committee responsible for finance, personnel and organisational and brings in practical experience from the association's work. The association invests around 4 million euros annually to support the national, European, and international standardisation work of NAM.[46]

Similar 'external' standards committees exist for the railway sector, road vehicle engineering (hosted by the German Association of the Automotive Industry, *Verband der Automobilindustrie*, VDA), air pollution prevention, iron and steel and machine tools. DKE – which is hosted by the association VDE – can be seen as a similar but more formalised standards committee since DKE is the German member of CENELEC and IEC.

4.4. Process of developing harmonised European standards

The European Commission uses harmonised European standards as a tool 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

46 Source: https://www.din.de/resource/blob/327344/587c454c228bed742c3e60894b0f077f/imagebroschuere-nam-data.pdf.

requirements in legislation. But only by applying harmonised standards that are cited in the OJEU, can manufacturers benefit from the presumption of conformity (see Chapter 3).

Harmonised European standards are requested by the European Commission

The European Commission drafts a standardisation request in consultation with the Member States and relevant stakeholders such as consumers, companies, industry associations and social partners. This consultation process is coordinated via the above mentioned EU comitology Committee on Standards chaired by the European Commission where German standardisation interests are represented and protected by the German Federal Ministry for Economic Affairs and Energy on behalf of Germany. If the Member States agree with the standardisation request, it is sent to the relevant European standardisation organisation – i.e. CEN, CENELEC or ETSI – for approval. The standardisation organisations are free to decide whether to accept or reject the request, depending on the conditions laid down in the request. However, a request is rejected only in exceptional cases on account of the prior consultation process.

A standardisation request can contain both existing and new standards, and European adoptions of international standards are often used (see Vienna and Frankfurt Agreements above). Once the European standardisation organisation has accepted the European Commission's request, the responsible technical committee adapts its work programme accordingly.

The development process of harmonised European standards and European standards follows the same principles and rules – in line with Regulation (EU) No 1025/2012 on European standardisation and the rules of procedure of the European standardisation organisations. As with any European standardisation project, once the respective European standardisation organisation starts a new project, a *standstill policy* and *implementation obligation* must be followed by the members. In accordance with the standstill policy, all national standardisation bodies must transfer their national standardisation activities within the project's scope to the European level. Based on the implementation obligation, CEN and CENELEC members must withdraw national conflicting standards and implement the European standard at national level once it is published.

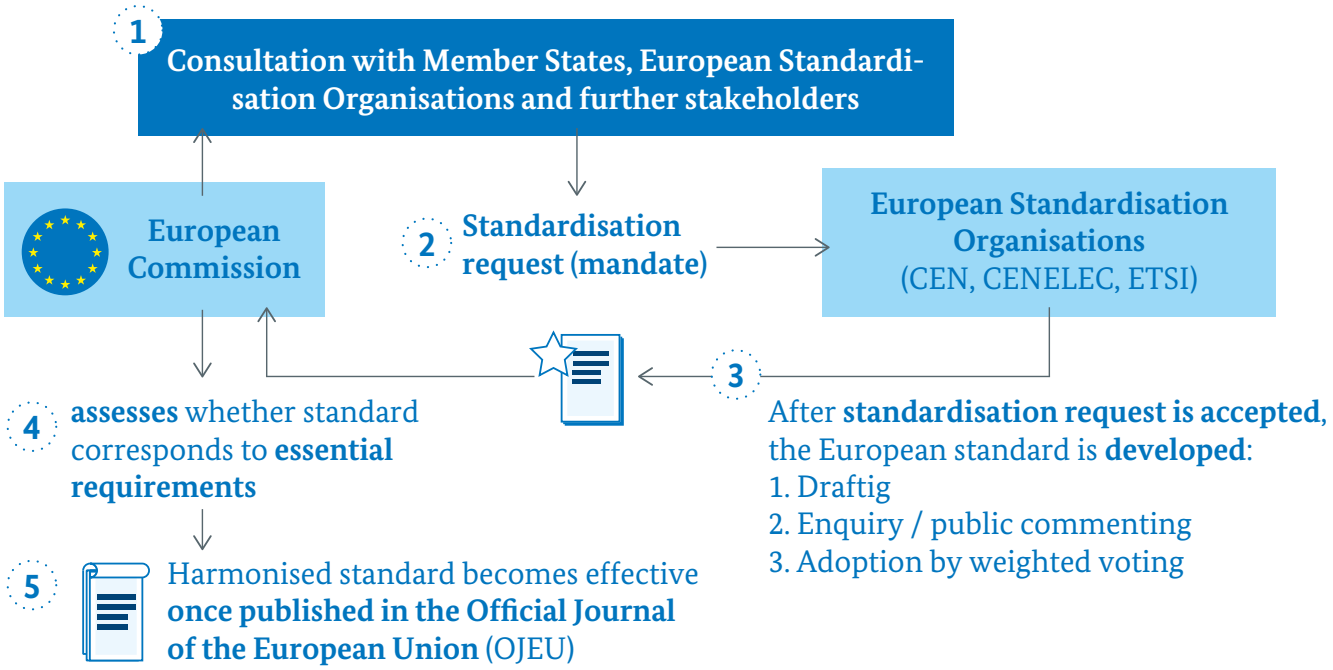
Assessment whether harmonised standards meet the requirements requested

In the case of harmonised standards, usually Harmonised Standards (HAS) Consultants – external service providers paid by the European Commission – assess whether the requirements and formalities determined in the standardisation request are addressed.

If they are assessed positively and the standard is voted and accepted through the public enquiry procedure by the national standardisation organisations, it will be offered to the European Commission for citation in the OJEU. At this point the European Commission will assess compliance with its initial standardisation request, i.e. conduct checks to determine whether adherence to the standard would result in essential requirements of the legislation being met. The Commission will only publish its reference in the OJEU if the standard meets the requirements of the standardisation request. Only once a harmonised standard is published in the OJEU, it allows for the benefit of presumption of conformity with essential requirements covered by the harmonised standard (see Chapter 3.3 for details on the presumption of conformity).

This, in essence, is the enormous benefit to legislators and the industry. The legislator does not have to deal with technical details and can instead make use of the expertise of the relevant interested parties. And the presumption of conformity gives industry the advantage of safe and easy access to the single market.

Figure 9: Simplified development process of harmonised standards



Source: Own representation.

Case studies: Where do I find harmonised standards that support me in complying with legislation?

Manufacturers are not obliged to use standards. But the use of harmonised standards listed in the Official Journal of the EU (OJEU) is beneficial because it leads to a presumption of conformity with the essential requirements for which the standard is applied. One consequence of this is a reduction in documentation requirements. On the website of the EU, you can find an overview of standards by sector and by product. This was published by the EU in its OJEU and can therefore be used for the presumption of conformity. The list of standards is available at https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en.

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Toaster

The following table provides an overview of harmonised standards which a manufacturer may use to ensure compliance with legal requirements. The standards depend on the essential requirements applicable and identified during the risk analysis and the specifics of the product. The OJEU indicates the versions (year) of the respective standards. These have been left out of the publication to avoid the need for frequent updating. Only the listed versions provide presumption of conformity.
The list is therefore for indicative purposes only.

Legislation	Indicative list of harmonised standards manufacturers may use
EMC directive	• EN 55014-1: Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission • EN 55014-2: Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity • EN 61000-3-2: Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions • EN 61000-3-3: Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems
LVD	• EN 60335-1: Household and similar electrical appliances – Safety – Part 1: General requirements • EN 60335-2-9: Household and similar electrical appliances – Safety – Part 2-9: Particular requirements for grills, toasters and similar portable cooking appliances • EN 61558: Safety of transformers, reactors, power supply units and combinations thereof • EN 62233: Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure
RoHS directive	• EN 63000: Technical documentation for the assessment of electrical and electronic products concerning the restriction of hazardous substances

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Electric motor

Harmonised standards available for the electric motor include the following:

Legislation	Indicative list of harmonised standards manufacturers may use
EMC directive	• EN 60034-1: Rotating electrical machines – Part 1: Rating and performance • EN 61000-3-2: Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions • EN 61000-3-3: Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems

LVD	• EN 60034: Rotating electrical machines; especially the following parts:
	  • Part 1: Rating and performance
	  • Part 5: Degrees of protection provided by the integral design of rotating electrical machines (IP code) – Classification
	  • Part 6: Methods of cooling (IC Code)
	  • Part 7: Classification of types of construction, mounting arrangements and terminal box position (IM Code)
	  • Part 8: Terminal markings and direction of rotation
	  • Part 9: Noise limits
	  • Part 11: Thermal protection
	  • Part 12: Starting performance of single-speed three-phase cage induction motors
	  • Part 14: Mechanical vibration of certain machines with shaft heights 56 mm and higher – Measurement, evaluation and limits of vibration severity

Ecodesign directive for electric motors	• EN 60034-2-1: Rotating electrical machines – Part 2-1: Standard methods for determining losses and efficiency from tests (excluding machines for traction vehicles) • EN 60034-30: Rotating electrical machines – Part 30: Efficiency classes of single-speed, three-phase, cage-induction motors (IE-code)

5. Conformity assessment and accreditation

Reliability through conformity assessment, trust through government-authorised accreditation.

Key points in this chapter

- The wide range of voluntary and mandatory conformity assessment in the EU reflects the various needs of an internationally oriented and modern economy.
- There is one government-authorised national accreditation body per EU Member State; these bodies are not allowed to compete or seek profit.
- The EU is committed to the international recognition of conformity assessment results based on international accreditation.

5.1. Overview of conformity assessment and accreditation

Conformity assessment creates trust in the quality and safety of products

Conformity assessment is the procedure by which compliance with specified requirements is demonstrated. These requirements may be defined through legislation, standards or other means. Conformity assessment increases reliability and objectivity when it comes to the quality and safety of products and services. For Germany's internationalised and modern economy, conformity assessment plays a crucial role not only in creating trust between market participants, but also in achieving public goals such as consumer safety and environmental protection.

There is a wide spectrum of conformity assessment in Germany and the EU. It can be categorised by the actors involved, the object assessed, types of assessment, legal requirements, specific accreditation requirements, and whether or not conformity assessment bodies have been granted legal authority to carry out specific assessments (see Figure 10).

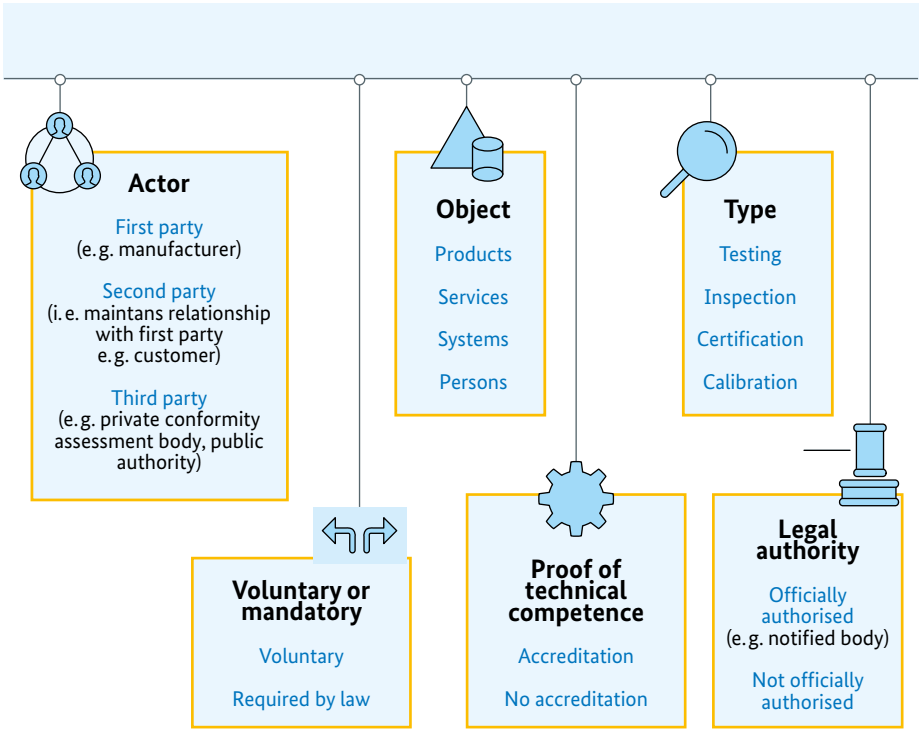
Conformity may be assessed by the first party, at a manufacturer's own testing laboratories for example. It may also be performed by the second party, who has a relationship with the manufacturer, e.g. client or a contracted entity on behalf of the client. Lastly, conformity assessment can be carried out by third-party bodies. These include private companies or public authorities which are independent from the organisations they examine.

Conformity assessment can be applied to products, services, systems and persons. It includes activities such as testing, inspection, certification and calibration. The need for conformity assessment and requirements may be demanded by law or it may be voluntary.

International accreditation organisations foster harmonisation in conformity assessment

Accreditation ensures that we can have trust in conformity assessment. Accreditation bodies attest the technical competence of conformity assessment bodies and their objectivity. In short: accreditation inspects those who inspect. This trust in conformity assessment is essential – no matter whether conformity assessment is required by law or not.

Figure 10: Categorisation of conformity assessment



Source: Own representation.

Through a network of international agreements, accreditation also ensures that conformity assessments are comparable and recognised internationally. This means conformity assessment procedures need not be duplicated unnecessarily, thereby easing international trade. The European and German accreditation systems are therefore embedded internationally as a result of their memberships of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). ILAC is responsible for international arrangements in matters of calibration, testing, medical testing, inspection and proficiency testing providers; IAF handles the certification of management systems, products, services and personnel, in addition to validation and verification (e.g. for greenhouse gas trading schemes). Currently, discussions are ongoing as to whether IAF and ILAC should be merged into one organisation.

IAF and ILAC manage mutual recognition agreements and multilateral recognition agreements (MRA and MLA respectively), which provide the framework for establishing international trust in conformity assessment through accreditation. They do this by integrating the relevant agreements between accreditation bodies at the regional level, such as the European co-operation for Accreditation (EA), Asia Pacific Accreditation Cooperation Incorporated (APAC) and the InterAmerican Accreditation Cooperation (IAAC).

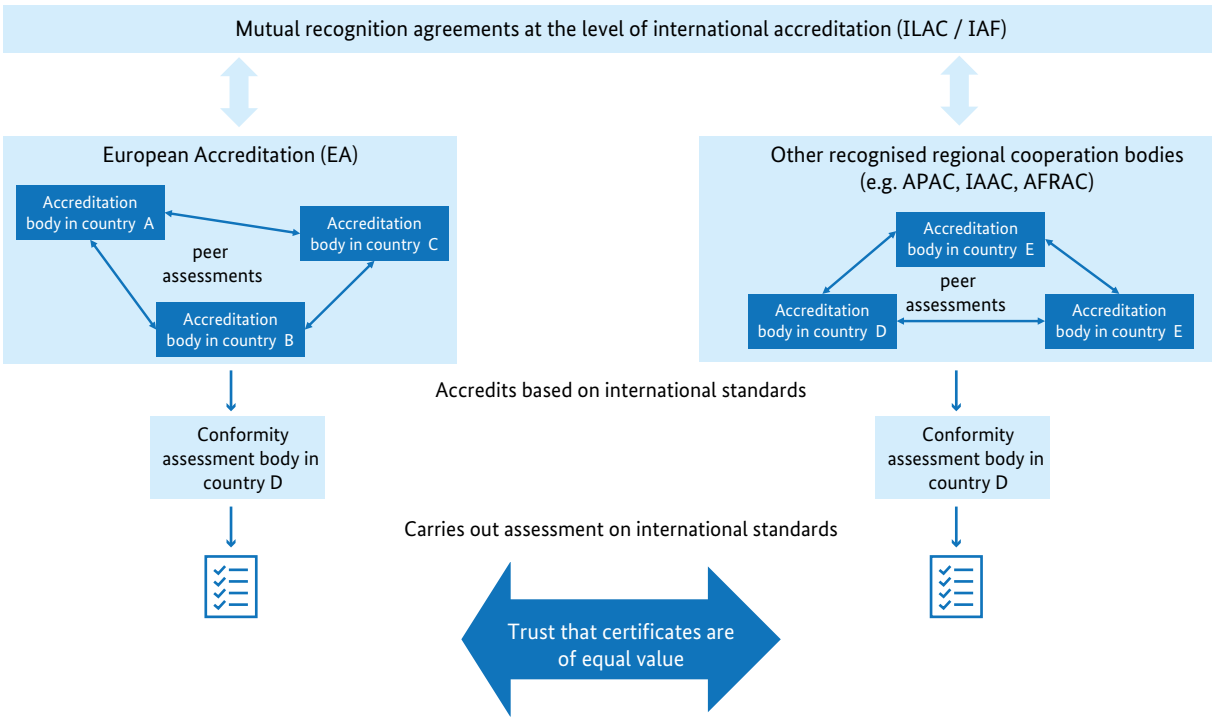
→ Please note that the term mutual recognition agreement (MRA) is used in various contexts. Information box 9 below sets out different forms of MRA.

National accreditation bodies can only become signatories to the IAF MLA and the ILAC MRA once they have passed a stringent peer evaluation by teams comprised of experts provided by other members. The members then agree that the accreditation of conformity assessment bodies – which is based on international standards – takes place at the same level of trust. This means that the accredited conformity assessment bodies are equal in terms of the technical competence and objectivity that is required. In this way, conformity assessment results can be treated equally, wherever the assessment took place. It does not matter whether a certificate was issued by conformity assessment body A or B, as they were held to the same stringent accreditation procedure by accreditation bodies that continuously assess each other (see Figure 11).

This system results in a strong network of trust that increases the quality of conformity assessments around the world and eases, lifts or prevents obstacles to international trade.

Local conformity assessment bodies may conduct assessments that meet the needs of international markets. Customers and authorities in other countries can trust in certificates issued by conformity assessment bodies that are accredited by members of such international agreements.

Figure 11: Mutual recognition based on international accreditation



Source: Own representation.

Information box 9: Various forms of mutual recognition agreements (MRAs)

Companies that operate internationally must comply with product legislation that may differ between countries. Even if legislative requirements are the same, if certain countries do not recognise earlier results, it may still be necessary to repeat testing and certification. This leads to unnecessary delays and additional costs. The purpose of mutual recognition agreements (MRA) is to overcome such unnecessary barriers. However, MRAs vary greatly in content and intent, so it is crucial to clarify what exactly is meant when using the term.

- **MRAs/MLAs based on international accreditation:** International recognition arrangements between accreditation bodies such as the ILAC Mutual Recognition Arrangement (MRA) and IAF Multilateral Recognition Arrangement (MLA) provide an established solution to avoid duplication of conformity assessments. They create mutual confidence in the quality of conformity assessment bodies accredited by its members: a conformity assessment body accredited by one signatory is considered equivalent to those accredited by other signatories to the arrangement. However, these arrangements are voluntary and often superseded by national regulations – e.g. if it is mandated that conformity assessment should be carried out by a body located in a specified country. Furthermore, in some cases accreditation may not be sufficient for a conformity assessment body to qualify to carry out assessments and further authorisation from a public authority is required (e.g. notified bodies, see Chapter 3.7).

- **MRAs between governments:** Another approach to reducing barriers to trade in relation to conformity assessments are agreements between governments. Through such agreements, one country may recognise the competence of another's conformity assessment bodies to perform testing and certification against their legislative requirements – thereby removing the requirement for bodies to be located within a country's territory but requiring compliance with that country's technical requirements and procedures. Such MRAs can be signed in the form of a bilateral governmental MRA (e.g. EU-Japan MRA) or as part of a multilateral (or regional) governmental MRA. They can also be signed as part of a free trade agreement (FTA). Governmental MRAs may also go one step further and treat each other's legislative requirements as equal – thereby accepting all conformity assessment results. In the EU, Member States can only enter into bilateral MRAs in areas not covered by EU harmonisation legislation.

- **Non-governmental arrangements:** Conformity assessment bodies themselves may also sign international agreements to have their test reports and certificates mutually accepted. A good example of such a private cooperative arrangement is the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE CB Scheme). The IECEE CB Scheme relies on trust-building through peer assessment among its members. Conformity assessment bodies that participate in such arrangements have a higher degree of credibility, being part of international expert networks and mutual assessments. It also enables them to carry out conformity assess-

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Information box 9: Various forms of mutual recognition agreements (MRAs) (cont.)

ments that are more widely accepted internationally – a competitive advantage valued by many manufacturers with international operations. However, while such arrangements strengthen trust in the technical competence of conformity assessment bodies, they are only voluntary in nature.

- **Mutual recognition principle in the EU single market:** It is important not to confuse the arrangements described above with the mutual recognition principle that guarantees free movement of goods on the EU single market. This principle applies to goods that are not – or only partly – subject to EU harmonisation legislation (see Chapter 2). It guarantees that a product that is lawfully sold in one Member State can also be sold in another, even if it does not fully comply with the technical rules of the other Member State. This principle is based on a much more fundamental form of mutual recognition, which not only includes the results of (accredited) conformity assessment, but also the applicable rules and regulations of the other country involved.

5.2. Accreditation in the EU

EU-wide principles establish accreditation as a layer of public control

In 2008, the EU created a uniform legal framework for accreditation by adopting Regulation (EC) No 765/2008. This framework reinforced accreditation as a means to attest technical competence for conformity assessment in both regulated and non-regulated sectors. It established the following principles:[47]

- **one accreditation body per country** – EU Member States shall not set up more than one national accreditation body each;
- **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 with it;
- **independence** – accreditation bodies shall be independent from 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.

In the EU, conformity bodies require only one accreditation issued by their national accreditation body which is recognised across the single market. This saves time and costs and strengthens the principle: accredited once, accepted everywhere.

47 For details, please refer to Regulation (EC) 765/2008.

Table 3: Scope and standards used for accreditation

Laboratories Testing and Medical examination (EN ISO/IEC 17025, EN ISO 15189) Calibration (EN ISO/IEC 17025)
Certification Bodies Product certification (EN ISO/IEC 17065) Certification of persons (EN ISO/IEC 17024) Management systems certification (EN ISO/IEC 17021-1)
Inspection Bodies Inspection (EN ISO/IEC 17020)
Validation and Verification Bodies Greenhouse Gas (GHG) Validation and Verification (EN ISO 14065)
Proficiency Testing Providers (PTP) Proficiency Testing Providers (EN ISO/IEC 17043)
Reference Materials Producers (RMP) Reference Materials Producers (EN ISO 17034)

Source: European Accreditation (EA).

To avoid harmful competition between the EU accreditation bodies, conformity assessment bodies can only seek accreditation from the accreditation body within their territory. A conformity assessment body may request an accreditation in another Member State only under very specific circumstances, as described in Regulation (EC) No 765/2008. This may be necessary and permissible in cases where the responsible accreditation body does not have the competence to carry out accreditation for a certain scope. In such a case, the two national accreditation bodies in question must cooperate and share information – upholding the principle of non-competition.

Peer evaluation of accreditation bodies creates a system of trust in Europe

Based on Regulation (EC) 765/2008, the European Commission appointed the European co-operation for Accreditation (EA) as an institution to build confidence among national accreditation bodies. To ensure an equivalent level of competence among its member bodies, EA uses a rigorous and transparent peer evaluation system – in line with procedures at the level of international accreditation (see pages 74/75). This system guarantees trust and confidence in the EA Multilateral Agreement (EA MLA), which EA members signed for specific scopes. EA MLA commits its signatories to treating each other's accreditation systems as equal. This means they also recognise the conformity assessment results of accredited bodies as equally reliable and trustworthy. In addition to EA full members, EA associate members such as Georgia and Ukraine have signed bilateral agreements with EA and benefit from the system of mutual trust.

EA peer evaluation checks that national accreditation bodies at all times comply with the relevant requirements, including those stipulated by Regulation (EC) 765/2008, by international standard EN ISO/IEC 17011, and by IAF and ILAC. The evaluation is carried out by highly qualified peer evaluators from other national accreditation bodies. It includes document reviews as well as on-site evaluations and witness assessments.[48] See Table 3 for the scope of EA MLA.

EA MLA is recognised by IAF and ILAC. The European accreditation infrastructure is internationally recognised and thereby supports international trade. International trust in accreditation by EA members means it is not necessary to duplicate the testing and certification of products already tested and certified by accredited conformity assessment bodies.

48 Detailed information about the peer evaluation can be found in the document "EA Procedure for the Evaluation of a National Accreditation Body" at https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-02.pdf (accessed in June 2020).

5.3. Accreditation in Germany

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 with each other and had overlapping areas of work. 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 German Federal Ministry for Economic Affairs and Energy), the Federal states[49] and industry (represented by the Federation of German Industries, *Bundesverband der Deutschen Industrie e.V.,* BDI). Each shareholder group holds a third of DAkkS shares.

The legal status of DAkkS facilitated a merger of the various accreditation bodies – which were previously partly private and partly state-owned – into one single organisation. This organisation was then appointed by the German Government to carry out the sovereign task of accreditation. The resulting organisation united the existing experience and expertise of several accreditation bodies under one roof.

Whereas DAkkS is subject to government supervision, its accreditation decisions are made independently and impartially. None of its shareholders can influence individual accreditation decisions. Its impartiality also means that DAkkS does not discriminate against any of its clients: its services are available to all conformity assessment bodies located in Germany.

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, any accreditation fees are based on German national legislation regarding fees and duties. DAkkS is also permitted to operate outside of its geographic scope and therefore outside the area for which it had primarily been authorised by the government. For such activities, fees are based on the fee schedule as prepared by DAkkS itself. For activities not directly related to accreditation or assessment activities – e.g. participation in committees – DAkkS receives funding from the Federal Government.

"Accreditation creates confidence in the work of conformity assessment bodies, whose services are needed in many sectors of the economy. As an accreditation body, we help to enhance the quality and safety of products and services. We act in the interest of governments, the global marketplace, as well as for the protection of consumers and the environment."

Dr Stephan Finke, CEO, DAkkS

49 The shareholding Federal States are Bavaria, Hamburg and North Rhine-Westphalia.

5.4. Voluntary conformity assessment in Germany

In addition to conformity assessment for products regulated by EU harmonisation legislation – covered in Chapter 3.2 – there is also a large market of voluntary conformity assessment in Germany. The presence of a variety of voluntary quality marks underlines the economic importance of activities such as testing, inspection and certification for businesses and consumers.

Even if not mandated by law, voluntary conformity assessment is of considerable significance to companies. In fact, 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 certain voluntary requirements (e.g. organic food certification).

Many organisations offer voluntary conformity assessment services. Any organisation can develop its own mark based on its own 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. In accordance with 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.

There are many private conformity assessment bodies in Germany which operate in regulated and non-regulated areas. These include for example 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 being public authorities – not least due to their testing and inspection work in regulated areas. However, they are private conformity assessment bodies.

This section gives two examples of quality marks which may be used voluntarily but have gained importance in Germany and beyond.

Table 4: Comparison of CE marking and GS mark

	CE Marking	GS Mark
Year of introduction	1993	1977
Use	Mandatory for products covered by EU harmonisation legislation	Voluntary
Conformity assessment	Different modules of conformity assessment, including manufacturer's declaration of conformity	Type approval by recognised third-party conformity assessment bodies
Target group	Market surveillance authorities	Consumers
Meaning	Demonstrates compliance with applicable EU harmonisation legislation	Proof of safety as per the German Product Safety Act

Source: Own representation based on TÜV Rheinland "CE marking and GS mark – the differences".

The voluntary GS mark based on the German Product Safety Act

GS mark: voluntary mark based on the German Product Safety Act

One established voluntary mark for product safety in Germany is the GS mark (GS stands for 'tested safety'; German: *geprüfte Sicherheit*). Manufacturers can use the mark to demonstrate that a product which is used as intended and in a foreseeable manner will not pose a risk to people's safety and health as set out in the German Product Safety Act (*Produktsicherheitsgesetz*, ProdSG). The GS mark was introduced in 1977 and is the only legally regulated product safety mark in Europe.

The GS mark requires type examination by a third-party conformity assessment body which is authorised to award the GS mark. The German Central Authority of the Federal States for Safety Engineering (ZLS) is responsible for recognising conformity assessment bodies. Manufacturers can apply for GS marking for any of their ready-to-use products. However, the GS mark may only be used for CE marked products where the GS mark covers additional requirements compared to the CE marking.

Unlike the CE mark, which informs market surveillance authorities, the GS mark targets consumers. So companies can use it in product advertisements, whereas use of the CE mark for product marketing is not allowed. Table 4 summarises the differences between CE and GS marks.

The Grüner Knopf mark for social and ecological sustainability

Grüner Knopf (Green Button)

A recently introduced voluntary mark is the *Grüner Knopf* (Green Button). It is a mark which denotes the social and ecological sustainability of textile products. The initiator and owner of the mark is the German Federal Ministry of Economic Cooperation and Development (*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung*, BMZ). Since its introduction in 2019, the mark has been helping consumers to identify sustainable products on the global market.

Grüner Knopf is the first federal mark to combine social and environmental requirements for both the product and the company. While textile production itself must adhere to environmental criteria, the company must guarantee implementation of corporate human rights and environmental due diligence in its supply chain.[50]

Use of the *Grüner Knopf* mark requires monitoring of compliance by independent certification bodies. These must be accredited by DAkkS. The criteria for certification are based on the United Nations' Guiding Principles on Business and Human Rights, as well as sector-specific recommendations by the Organisation for Economic Co-operation and Development (OECD)[51]. As the certification carried out is based on international standards, the mark can be used in Germany and elsewhere by both German and foreign companies.

50 A list of the requirements can be found on the official Grüner Knopf Website.

51 OECD Due Diligence Guidance for Responsible Supply Chains in the Garment and Footwear Sector.

Any company that manufactures textile products, as well as trading companies that sell third-party products as private labels, can apply for the *Grüner Knopf* mark. Similar to the GS mark, the *Grüner Knopf* mark can be used in advertisements. It also qualifies a product for green public procurement in the EU.[52]

5.5. Conformity assessment by public bodies in Germany

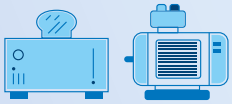
Governments in the EU have over time delegated more and more conformity assessment activities to private-sector bodies rather than carry them out themselves. The system of government-authorised accreditation and notification of conformity assessment bodies by public authorities has proven to be effective in guaranteeing high-quality and trusted services by the private sector – even for high-risk areas such as chemical or medical equipment.

In some sectors, government bodies carry out conformity assessments themselves: the German Metrology Institute (PTB) for example carries out conformity assessments in the field of legal metrology (e.g. type examination of energy measuring instruments) and the Federal Institute for Materials Research and Testing (BAM) carries out conformity assessments in the field of technical safety, including containers for dangerous goods (e.g. CASTOR containers) or explosive substances.

Public bodies commonly carry out conformity assessment 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 is publicly funded (as in case of BAM and PTB). It may also be that some assessments are not sufficiently economical to be offered by the private sector if investment in testing infrastructure is too great in relation to the expected volume of tests.

Case studies: What is the role of third-party conformity assessment and accreditation in complying with EU product legislation?

Third-party conformity assessment and accreditation create reliability and trust in products. As outlined in the previous chapter, in our case studies the manufacturer need not involve a third-party conformity assessment body, i.e. a notified body. However, some legislation offers the option to involve a notified body during conformity assessment. Of course, manufacturers can always voluntarily involve a third-party conformity assessment body if they require support.



Toaster and electric motor

For illustrative purposes, we are looking only at conformity assessment requirements in the context of the EMC directive. Given that both products in our case studies must comply with this directive, we will consider the toaster and electric motor together.

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52 Information is taken from Grüner Knopf Website.

The EMC directive offers two options during conformity assessment – both of these cover the design phase and production phase: internal production control (Module A) or a combination of EU type examination (Module B) and conformity to type (Module C). Please find an overview in the table below.

Module A:
If manufacturers choose the first option, they can create the technical documentation themselves during the design phase and take necessary measures to ensure that the manufacturing process complies with the technical documentation. No third-party conformity assessment – i.e. notified body – is involved.

Module B + C:
If manufacturers choose the second option, then a notified body is involved during type examination (design phase). Creating the technical documentation is still the responsibility of the manufacturer. But a notified body – chosen by the manufacturer – examines whether the technical documentation shows a product that complies with the essential requirements applicable. The EU type examination may also involve examination of a product specimen and not just the technical documentation – this is defined in the respective legislation. The EMC directive requires only a type examination based on the manufacturer's technical documentation and no product specimen.

After the examination, the notified body writes an evaluation report. If the examination was successful, the notified body issues the manufacturer with an EU type examination certificate. Notified bodies must inform notifying authorities – in Germany this is the Bundesnetzagentur (BNetzA) – about certificates it refuses to issue or withdraws. If the notified body refuses to issue a certificate or withdraws one, it additionally informs other notified bodies.

In option 2, the production phase follows the same logic of the internal production control. The manufacturer must take all necessary measures to ensure that production complies with the now certified technical documentation – no notified body is involved in the production phase.

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Table 5: Two conformity assessment options for the EMC directive

	Design phase	Production phase
	Module A: Internal production control	
Option 1	• Manufacturer creates the technical documentation (incl. risk analysis, applicable essential requirements, information on design, manufacture and operation of the product).	• Manufacturer takes necessary measures to ensure that the manufactured product complies with the one outlined in the technical documentation.
Option 2	**Module B: EU type examination** • Manufacturer creates the technical documentation. • Notified body examines the technical documentation (no specimen). Is the design adequate to fulfil the essential requirements? • Notified body creates an evaluation report. • If evaluation was successful, the notified body issues the manufacturer with an EU type examination certificate. • Notified body informs its notifying authority about the issuing (or refusal) of a certificate. • If the notified body refuses or withdraws a certificate, it informs other notified bodies.	**Module C: Conformity to type** • Manufacturer ensures and declares that the manufactured products are in compliance with the type described in the EU type examination certificate during Module B. • No involvement of a notified body.

Source: Own representation.

Accreditation

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. There are currently ten notified bodies in Germany that are approved for the EMC directive by the Bundesnetzagentur, the notifying authority responsible in Germany. During the evaluation process of a body seeking to become a notified body, the Bundesnetzagentur checks whether it complies both with the requirements set out in the EMC directive and with relevant standards. As part of its assessment, the Bundesnetzagentur also considers any accreditation certificates as per EN ISO/IEC 17025, if available. Even though accreditation is not mandatory, in practice some notified bodies are accredited.

What is the role of voluntary third-party conformity assessment?

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

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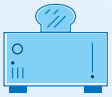

Toaster

In Germany, there are many private conformity assessment bodies offering services to test appliances such as toasters and subsequently award their own quality mark. While it is up to the manufacturer to contract any conformity assessment body, only accredited bodies will have passed an independent evaluation of their technical competence. In view 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. Our focus here is not on any particular private quality mark, since there are many such quality marks competing in a free market.[53]

The toaster may also benefit from the voluntary GS mark, which demonstrates compliance with the German Product Safety Law. It is the only legally regulated product safety mark in Europe and widely used with consumer products. The GS mark can be used together with the CE marking, but only if requirements for the GS mark are higher than those for the CE marking.

To obtain a GS marking, the manufacturer must implement a set procedure:

1. The manufacturer selects a conformity body authorised by ZLS to award the GS mark. A list can be found on the website of the German Federal Institute for Occupational Health and Safety (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin; BAUA). There are around 50 conformity assessment bodies in Germany authorised to award the GS mark (i.e. GS bodies).

2. The manufacturer (or the authorised representative) sends an application to the GS body.

3. Through a type examination, the GS body assesses whether the toaster complies with the requirements of the German Product Safety Law and other relevant requirements concerning health and safety.

4. The GS body assesses whether the manufacturer can guarantee that production of the toaster conforms with the tested type.

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53 This publication does also not cover other schemes that support the international recognition of test reports, such as the CB Scheme of the IEC System of Conformity Assessment Schemes for Electrotechical Equipment and Components (IECEE). The IECEE CB Scheme is an international system for mutual acceptance of test reports and certificates in the field of safety of electrical and electronic products. Rather than relying on accreditation, the IECEE CB Scheme uses a peer assessment system among participating bodies to create trust in conformity assessment results.

5. If the manufacturer successfully passes the type examination and fulfils all conditions to manufacture compliant products, the GS body issues a GS certificate. The manufacturer can then affix the GS mark to the product, its packaging or use it in advertising material. The GS mark is valid for five years and carries information about the GS body involved.

6. The GS body carries out market surveillance, checks whether GS marked products are compliant and that the GS mark is being used correctly.

Electric motor

The GS mark is primarily for consumer products and therefore not available for electric motors. A common voluntary certification sought by manufacturers of electric motors is the certification of their quality management system in line with the ISO 9000 series of standards. Since this is already a well-known certification, we will not provide specifics in this publication.

6. Metrology

Measurement that keeps up with scientific progress is an important foundation of quality infrastructure and facilitates trade.

Key points in this chapter

- 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 at 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. accuracy of measurements and labelling of prepacked products – is a building block of the EU single market.

6.1. Introduction

To measure is to know: metrology affects most aspects of our life

Does 1 kg weigh the same in one country as it does in another? Can I trust a measuring instrument to show the correct lead content in my drinking water? Is that clock fast or is my train behind schedule? We use measurements every day – we depend on them if society and the economy are to function. And consequently we depend also on the science of measurement and its applications: metrology.

We can specify and value products only if measurements are accurate and comparable, for example if we know their exact size and weight. Two things are essential for this: research and development, and international cooperation. Through research and development, metrology can keep up with technologies that are constantly evolving. On the other hand, international cooperation is crucial if measurements are to be comparable. For this reason, a country's national metrology system must be embedded internationally if it is to serve an economy with a global perspective.

The international system of units (SI) was developed to ensure that measurement results are reliable. This system forms the basis for measurements in countries around the globe – including the EU – and supports international trade. Consequently, almost every country in the world has a metrology institute. These institutes are responsible for the realisation and dissemination of units (e.g. kilogram, metre, second) and cooperate internationally to compare their national measurement standards. The *Physikalisch-Technische Bundesanstalt* (PTB) is Germany's national metrology institute. The founding of PTB's predecessor organisation dates back to 1887.

Legal, industrial and scientific metrology

In the EU and Germany there is a clear distinction between legal, industrial and scientific metrology:

- **legal metrology:** regulatory requirements for measurement units, instruments and methods;
- **industrial metrology:** application of measurements in industry and society, e.g. for quality control;
- **scientific metrology:** establishment and maintenance of measurements units and standards.

6.2. EU and German participation in international metrology

Given their economies' focus on international markets, Germany and the EU have become drivers of continuous improvements in metrology and efforts to strengthen the international metrology network, in particular through the Metre Convention and the International Organization of Legal Metrology (OIML).

CIPM MRA: equivalent measurement standards and certificates

The Metre Convention is an international treaty signed in 1875 that promotes the metric system and today has more than 60 members. The treaty established the International Bureau of Weights and Measures (French: *Bureau international des poids et mesures*, BIPM) which serves the international metrology community to make measurements comparable at a global level.

Its members set up an international framework through which national metrology institutes can demonstrate to each other the equivalence of their measurement standards as well as of their calibration and measurement certificates. This framework is known as the Mutual Recognition Arrangement (MRA) of the International Committee for Weights and Measures (CIPM). Within this arrangement, PTB and other national metrology institutes undergo regional and international peer reviews to approve their calibration and measurement capabilities.

After successfully completing the review process, national metrology institutes can register relevant technical information about their capabilities on a global online database.[54] This is the basis for international acceptance of a metrology institute's measurement results. The CIPM MRA was signed by representatives of 106 institutes in more than 100 countries. In addition, it covers a further 152 institutes which have been designated by the signatory bodies.[55]

OIML-CS: supporting the international trade of regulated measuring instruments

Germany also plays an active role in the OIML certification system for regulated measuring instruments. This allows Germany to issue internationally recognised test reports and to accept those from other countries taking part in this system. The OIML certification system (OIML-CS), which replaced two earlier OIML arrangements, was introduced in 2018.

OIML-CS aims to harmonise technical requirements for regulated measuring instruments at the international level. In so doing, it supports the principle that legal metrology requirements for measuring instruments are interpreted and implemented equally around the world. In addition, OIML-CS supports the international trade in measuring instruments, since manufacturers require only one OIML certificate, which is then recognised by other participating members.

There are two key groups of participants in OIML-CS: issuing authorities and utilisers.[56] Any authority seeking the right to issue OIML certificates must first demonstrate compliance with international requirements for conformity assessment bodies according to ISO/IEC 17065, and then pass a peer-

54 This database is the BIPM key comparisons database (available at www.bipm.org/kcdb).

55 Source: https://www.bipm.org/en/cipm-mra/.

56 For reasons of simplicity, this overview left out participants with the status "associate" because these are comparable to utilisers – but without voting rights on the scheme's management committee.

evaluation or accreditation.[57] To become a utiliser within OIML-CS, authorities must sign a declaration committing them to voluntary acceptance and utilisation of OIML type evaluation and test reports.

6.3. Legal metrology in the EU

Uniform units and accurate measurements across the EU

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.[58] The uniform implementation of these directives across the EU is supported by guidance documents developed by the European Commission and the European Cooperation in Legal Metrology (WELMEC)[59] – a European platform connecting legal metrology organisations from 39 countries.

Example of CE marking together with the metrology marking according to Directives 2014/32/EU and 2014/31/EU.

Directive 2014/32/EU sets rules (e.g. essential requirements) for measuring instruments placed on the market and put into use in the EU. It covers, for example, gas and water meters, measuring systems for petrol pumps, automatic weighing instruments and taximeters. Directive 2014/31/EU governs non-automatic weighing instruments, i.e. those that require human intervention during weighing, such as when weighing patients.

In addition to the CE marking, the directives require manufacturers to add the supplementary metrology (M) marking, together with the last two digits of the year in which the marking was affixed and the 4-digit number of the notified body involved (see example on the left).

What's in the box? Consumers in the EU know the answer

Users of prepacked products want to know how much content is inside. The EU therefore regulates the labelling of prepacked products when the content is between 5 g and 10 kg in weight or 5 ml and 10 l in volume. The label must show the product's weight or volume and take account of certain metrological conditions. In such cases three directives apply:

- Directive 76/211/EEC – making-up prepackaged products (by weight or volume)
- Directive 75/107/EEC – bottles used as measuring containers
- Directive 2009/34/EC - Framework Directive on measuring instruments and metrological control methods

57 For some types of measuring instruments, no peer assessment or accreditation is required and a self-declaration is sufficient.

58 In Germany, the directives are enacted through the Measuring and Verification Law (*Mess- und Eichgesetz*, MessEG).

59 The acronym WELMEC stems from its former name: *Western European Legal Metrology Cooperation*.

The ‘e’ mark as specified in Annex II of Directive 2009/34/EC.

To ease the movement of prepacked products on the single market, the EU introduced a voluntary ‘e’ mark (for estimated quantity). By placing the ‘e’ mark next to the nominal weight or volume, the packer or importer of a product gives an assurance that prepackages meet the requirements of Directive 76/211/EEC on quality and metrological controls – e. g. content does not vary beyond defined thresholds. Similar to the CE marking, the ‘e’ mark is like a metrological passport within the EU single market. Directive 75/107/EEC established a similar marking in the shape of a reversed epsilon (ɜ) for glass bottles.

6.4. Overview of metrology in Germany

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 Energy (BMWi).

“No nation can prosper without a solid international base for measurements. A digital world with billions of sensors calls for trust in the measured values created by metrology.”

Prof. Joachim Ullrich, President, PTB

Based on its mandate, PTB provides a reliable and internationally recognised metrological infrastructure for the economy, for science and research, and for society in general. 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.

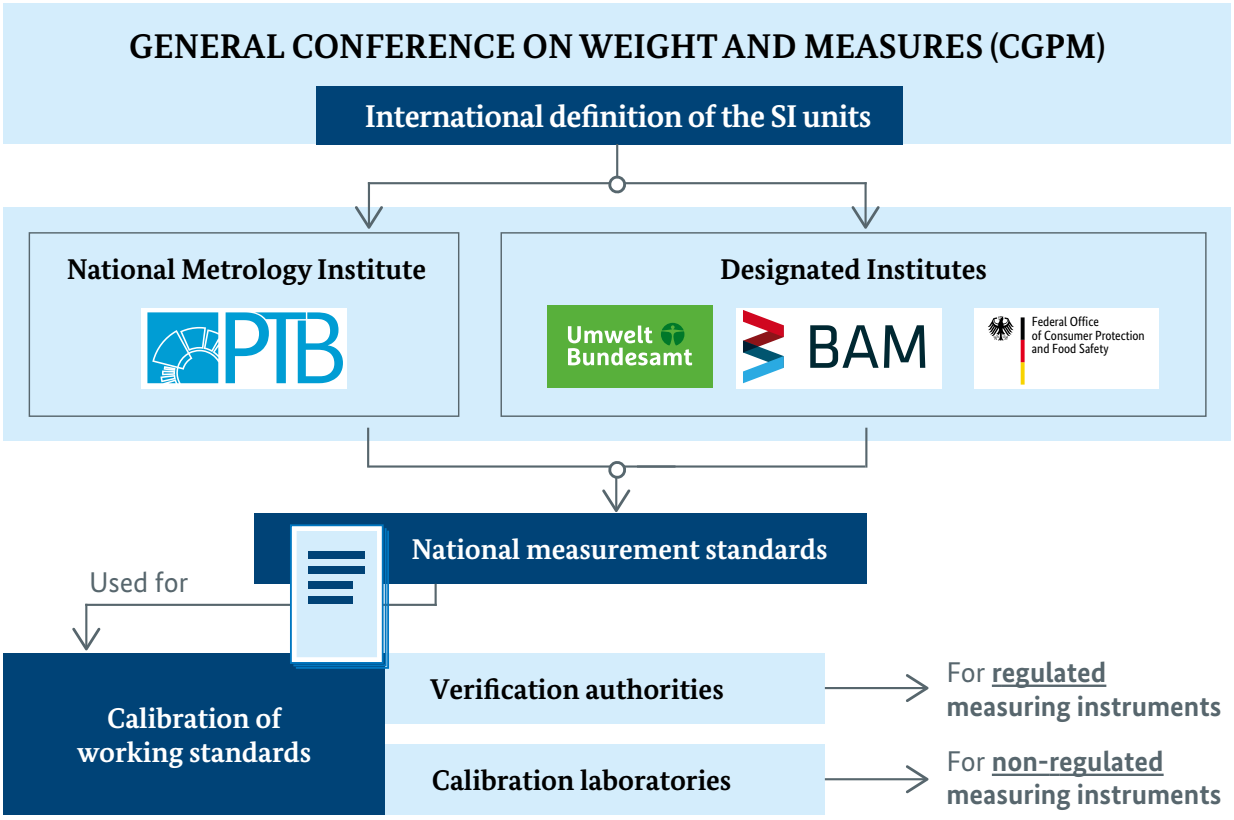
PTB and designated institutes guarantee the chain of measurement standards

Measuring instruments are only accurate if they use the latest and most accurate measurement standards. At international level, SI units are defined by the General Conference on Weights and Measures (CGPM) based on the Metre Convention (see page 88). Together with three designated institutes, PTB is responsible for providing 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 (see Figure 12).

Figure 12: Chain of measurement standards in Germany



Source: Own representation.

Verification and calibration of measuring instruments in Germany

Germany implemented Directives 2014/31/EU and 2014/32/EU for measuring instruments and non-automatic weighing instruments by revising its Measuring and Verification Law (*Mess- und Eichgesetz*, MessEG) and corresponding regulations. 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.

MessEG also ensures that measuring instruments put into operation in Germany can be trusted over their entire lifetime – i.e. that measurements taken are always accurate with given limits. 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 re-verified by verification authorities and officially recognised testing bodies (this applies to utility meters only) (see Figure 13). These verification authorities are established at federal state level.

Whereas EU harmonisation legislation applies to *manufacturers* that place measuring instruments on the market, MessEG places the responsibility on users of measuring instruments and manufacturers producing nationally regulated measuring instruments. An initial verification of the measuring instrument is not required for new measuring

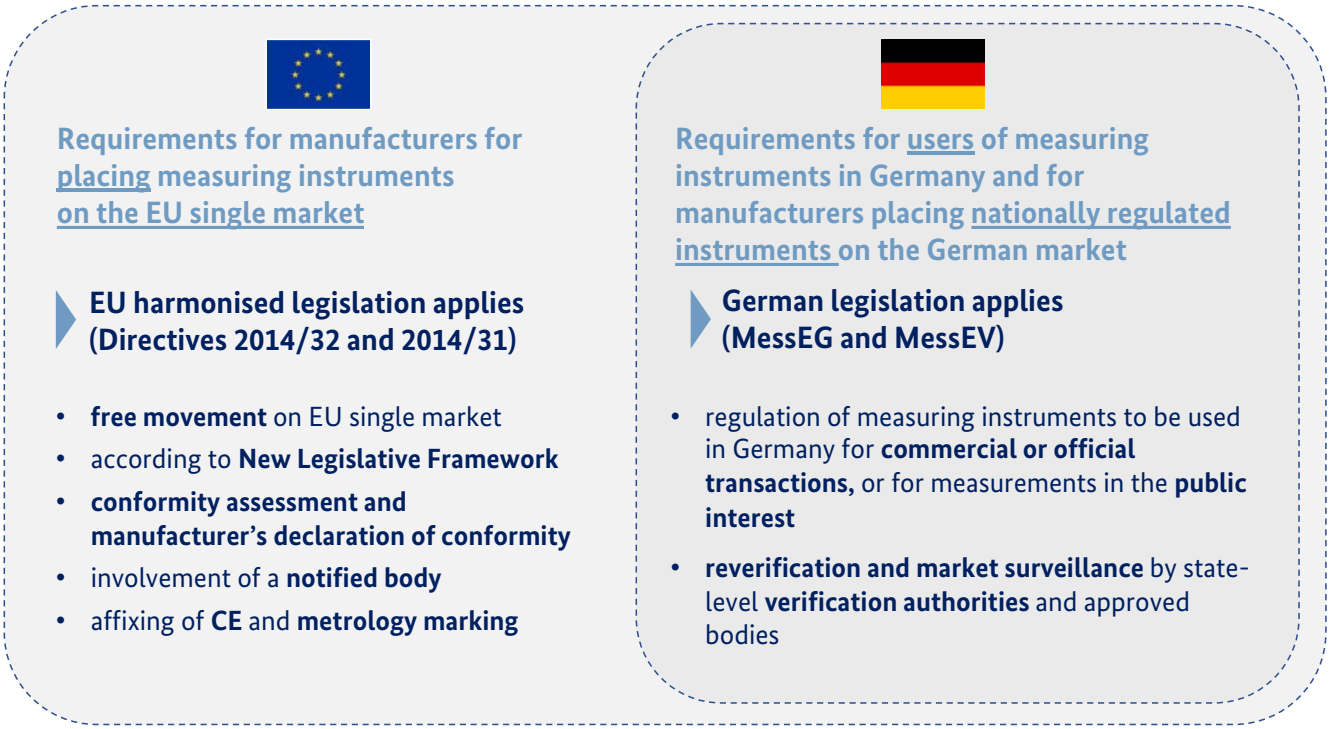
instruments, since the manufacturer must carry out conformity assessment prior to placing it on the market. However, users of new or renewed measuring instruments must inform the responsible state-level verification authority no later than six weeks after putting the instrument into operation. This ensures that verification authorities can carry out their market surveillance of measuring instruments effectively.

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. Reference materials are materials or substances which have a specific degree of homogeneity and in which one or several properties have been determined with such accuracy that they can be used as references, e.g. to calibrate measurement devices or assess measurement techniques. In Germany, BAM provides its clients in 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 for polymers.

Reference materials guarantee that measurement results can be compared with recognised reference values. They are frequently used for determining measurement uncertainty, calibration and validation of methods, suitability testing and quality assurance. The use of (certified) reference materials for quality assurance is a requirement (under ISO 17025) for accredited testing and calibration laboratories.

Figure 13: Legislation for measuring instruments in Germany and the EU



Source: Own representation.

For example, reference materials are important in implementing the requirements of the Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU that limits dangerous amounts of substances such as lead or cadmium in electrical and electronic equipment.

"Safety creates trust and trust creates markets. BAM supports the continuous improvement of safety in technology and chemistry. For this, we increasingly put emphasis on the benefits of digitalisation – be it through predictive maintenance or the digitalisation of quality infrastructures."

Prof. Ulrich Panne, President, BAM

BAM can draw on over 100 years of expertise in the area of developing and certifying reference materials and is accredited by DAkkS as a producer of reference materials in accordance with ISO 17034 (General requirements for the competence of reference material producers). The reference materials are certified in line with the principles and requirements of ISO 17034 and ISO Guide 35. When developing reference materials, BAM relies on many years of collaboration with accredited laboratories as well as measuring expertise as a designated institute for metrology in the field of chemistry. BAM regularly participates in round robin tests to validate testing methods or the characteristics of reference materials, and prove suitability for measurement purposes (e.g. within CCQM – the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology of the BIPM).

Germany's leading role in metrological research and development

PTB contributes to the harmonisation and further development of metrology. So, research and development are part of PTB's legal mandate and account for two thirds of its activities.[60] PTB is an active member of the two European metrology organisations: the European Association of National Metrology Institutes (EURAMET) for non-legal metrology, and the European Cooperation in Legal Metrology (WELMEC)[61] 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 industry. PTB offers a variety of services to calibrate many different measurement standards and advises a range of stakeholders, including ministries, industry, accredited calibration laboratories, verification authorities, universities and research institutions.

One specific task given to PTB by law is the technology transfer of newly developed metrological technologies to industry. PTB holds more than 150 patents and gives licenses to interested companies. The spread of technologies is supported by the funding programme TransMeT – Transfer of Metrological Technologies of the Federal Ministry for Economic Affairs and Energy (BMWi). Small and medium-sized enterprises can apply for funding to collaborate with PTB on turning new metrological technologies into products.

In the field of industrial metrology, PTB cooperates closely with the industry itself and with around 400 accredited calibration laboratories. These laboratories are members of the German Calibration

60 https://www.ptb.de/cms/fileadmin/internet/publikationen/broschueren/Infoblatt_Die_PTB_D.pdf.

61 The acronym WELMEC stems from its former name: Western European Legal Metrology Cooperation.

Service (*Deutscher Kalibrierdienst*, DKD), a professional forum that works towards harmonising the calibration sector and supports the quality of calibration services in Germany.[62]

In the field of scientific metrology, PTB and the designated institutes (i.e. BAM, BVL, UBA) conduct many research projects with national and international partners, in particular under the European Metrology Program for Innovation and Research (EMPIR) funded by the EU.

PTB's multi-faceted international cooperation

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

PTB has also signed many bilateral cooperation agreements on scientific metrology and invites colleagues from all over the world to become guest researchers at PTB (see information box on the right).

Finally, PTB is involved in international technical cooperation on quality infrastructure. Commissioned by the German Federal Ministry for Economic Cooperation and Development (*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung*, BMZ), PTB currently carries out more than 40 projects in over 90 countries (see on the right).

PTB's guest researcher programme

- open to **scientists and engineers working in metrology**, e.g. from national metrology institutes, designated institutes, or other scientific or technological institutions;
- establishing an **international network of metrologists** and facilitating international collaboration;
- research stays of between **1 and 8 months**;
- PTB **compensates** for **expenses in Germany**.

Please visit www.ptb.de for further information.

International technical cooperation of PTB

- helping partner countries to establish national quality infrastructures (e.g. metrology institutes, accreditation and standardisation bodies, market surveillance authorities, calibration and test laboratories);
- helping quality infrastructure institutions to achieve international recognition.

62 PTB-Mitteilungen Vol. 03/2019: The new German Calibration Service (DKD) – A success story continues, available at https://oar.ptb.de/files/download/56d6a9caab9f3f76468b45c1.

Case studies: What is the role of metrology for the two case studies?

Accurate and internationally comparable measurements are crucial to our two case studies. Here we illustrate aspects of metrology in certain key areas.

Toaster

What is the precise electrical power of a toaster? Can we be sure it is 1,000 watts, or could it be 1,050 watts? And does measuring electrical power in different countries lead to the same results? An international chain of measurement standards ensures that manufacturers and conformity assessment bodies use accurate measuring instruments – including wattmeters for electrical power. For this reason, as described above, the EU regulates the verification and calibration of measuring instruments through Directive 2014/32/EU.

A 'calibration pyramid' ensures that measurement instruments used by manufacturers and conformity assessment bodies are calibrated by accredited calibration laboratories. These laboratories themselves derive their accuracy from national measurements standards which are based on international definitions of the SI units. PTB regularly participates in peer reviews to verify the international comparability of measurement standards.

In addition to obtaining precise results for electrical power, for the toaster 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 toaster 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 is it possible to detect levels that would be dangerous to humans and the environment. Certified reference materials provided by BAM are therefore crucial for accredited laboratories measuring the amount of substances such as lead in toasters.

Electric motor

Electric motors must comply with strict limits set down in the EMC directive. Manufacturers therefore require a precise measurement of electromagnetic fields that electric motors emit and test whether their motor is immune to other electromagnetic fields. Manufacturers often rely on third-party testing laboratories for such measurements, since they usually require elaborate testing facilities. The measuring instruments used by testing laboratories must be calibrated by accredited calibration laboratories. These laboratories receive their measurement standards from PTB, which in turn derives them from international definitions of the SI units.

7. Market surveillance

The EU's risk-based post-market surveillance system implemented by Member States ensures fair competition and enables the free movement of goods that are safe and conform to legislation.

Key points in this chapter

- The EU system relies on the implementation of market surveillance by the authorities of Member States that are close to the markets; in Germany these include state-level agencies and the decentralised regional offices of governmental authorities.
- A risk-based approach and use of market intelligence combined with long-term experience are key to targeting market surveillance activities effectively in the EU.
- The EU has set up systems to share information and experiences rapidly and ensure effective and efficient cross-border market surveillance.
- Market surveillance in the EU adapts to emerging trends such as e-commerce.

7.1. Overview of market surveillance in the EU

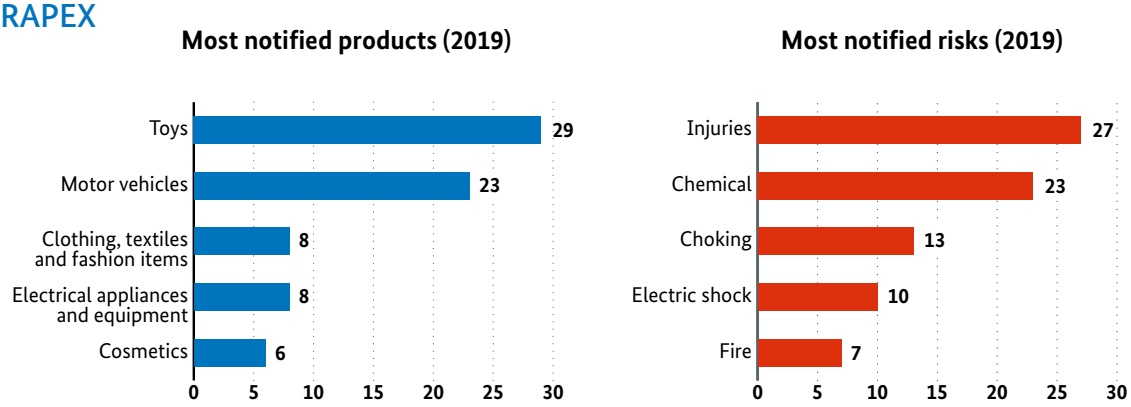
Market surveillance ensures safety, fair competition and the free movement of goods

Even with standards and conformity assessment in place, it is possible for non-compliant products to arrive on the market. Children may choke on parts of toys that break off easily. An overheating smartphone battery can be a safety or fire hazard. Shoes that contain toxic substances pose health risks. In cases such as these, market surveillance is required. The role of market surveillance authorities is therefore to watch the market closely and request manufacturers to recall or withdraw products that are dangerous or do not comply with EU legislation. In so doing, they perform a crucial task for the safety of European citizens.

This makes market surveillance an essential pillar of the EU's quality infrastructure. As the last link in the EU quality chain, market surveillance enables products to circulate freely on the single market, while ensuring that these result neither in injury, nor violate other public interests by causing environmental damage or posing a threat to security, for example. Businesses also benefit from market surveillance because it protects them against unfair competition – from those who do not follow the rules.

So what products do market surveillance authorities in the EU most frequently identify as ones that pose a serious risk to consumers? In 2019, toys and motor vehicles accounted for 29 percent and 23 percent respectively of all notifications through the Rapid Alert System (RAPEX), which is used by authorities to inform other member countries about a serious risk (see pages 104/105 for more information about RAPEX). The relatively high prevalence of toys in this statistic reflects the authorities' focus on the safety of vulnerable groups such as children – it does not indicate that toys are generally of lower quality than other products. Other product categories which were frequently found to be non-compliant include clothing, textiles and fashion items (8 percent), electrical appliances and equipment (8 percent) and cosmetics (6 percent). The most common risks associated with dangerous products

Figure 14: Most common products and risks notified by EU market surveillance authorities through RAPEX



Source: European Commission, 2020: 2019 results of the Rapid Alert System. Accessible online at https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/RAPEX.2019.report.EN.pdf

relate to injuries (27 percent), chemicals (23 percent), choking (13 percent), electrical shock (10 percent) and fire (10 percent).

As outlined in Chapter 3, manufacturers are fully responsible for ensuring that their products conform to EU legislation. Market surveillance generally starts *after* a manufacturer has placed a product on the market – there are no controls *prior* to this in the NLF system. The EU system is therefore a *post*-market surveillance system. For this reason, market surveillance should not be confused with the risk and conformity assessment which manufacturers conduct before a product is placed on the market, sometimes with support from third-party conformity assessment bodies.

It makes no difference whether an economic operator makes a product available on the market through bricks-and-mortar retail, online platform or any other means of distance selling. All products must comply with EU legislation if they are offered to and target end-users in the EU. Authorities assess this on a case-by-case basis, for example by considering possible supply regions, available languages for the product or payment methods.[63]

EU-wide market surveillance framework – but implemented by Member States

The EU Member States are responsible for implementing market surveillance. National authorities know their markets best and so have a better sense of how to identify non-compliant products. However, legal requirements are the same across the EU to guarantee an equal level of protection, regardless of a product's origin. The legal basis for market surveillance is set out in Regulation (EC) No 765/2008 and its amendments in Regulation (EU) 2019/1020. Although the amended regulation only entered into force on a step-by-step basis between January and July 2021, reference is made to the amended market surveillance system in this current publication.

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. Further-

63 The EU introduced the equal treatment of products sold online and offline with Regulation (EU) 2019/1020. This publication makes reference to this new legislation here, even though it only enters into force between January and July 2021.

more, they are required to establish a system of sanctions per EU legislation. Authorities in Member States must monitor their market, create strategies on how 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.

You can't check everything: key principles for successful market surveillance

Ensuring that all products on the market are safe and in compliance is a colossal task. In order to be effective and use public resources efficiently, therefore, authorities need to select their activities wisely. Key principles to help EU market surveillance authorities achieve this include:[64]

- **Strategy:** National authorities must prepare market surveillance strategies and update these at least every four years. The strategies provide information about the national authorities responsible, sectors in which they conduct market surveillance, chosen market surveillance approaches and documentation of any previous actions. National authorities are required to make these strategies available to the public.[65]

- **Risk-based approach:** 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, an economic operator's record of non-compliance, the extent to which an economic operator can control activities and operations, and other information such as consumer complaints.[66]

- **Proportionality:** The EU requires national authorities to take appropriate and proportionate corrective action to end non-compliance or eliminate the risk posed by a non-conforming product.[67] This means national authorities should apply only necessary force, for example, by requiring the economic operator to include a risk warning label on the product, bring the product into compliance, prevent product availability, or withdraw, recall or even destroy a product that is deemed dangerous.

- **Involving economic operators:** National authorities can maximise the effectiveness of their market surveillance by involving all the economic operators responsible for a non-compliant product. Both the economic operators and the national distributors (i.e. any other actor in the supply chain who makes the product available on the market) will always be required to take corrective action. EU legislation stipulates clear responsibilities on the part of economic operators; these include providing market surveillance authorities with information about their supply chain if required.

- **Cross-border cooperation:** While national authorities are responsible for market surveillance, the EU is a single market. It is therefore essential for national authorities to cooperate with each other, e.g. through timely exchange of information. A shared Information and Communication System for Market Surveillance

64 See also ZLS, 2016, Good Practices for Market Surveillance, available at http://www.zls-muenchen.de/marktueberwachung/richtlinienvertreter/richtlinienvertretung_druck/dokumente/Good%20practice%20for%20market%20surveillance_EN.pdf.

65 The strategies can be downloaded at https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en.

66 See Regulation (EU) 1020/2019, Article 11(3).

67 See Regulation (EU) 1020/2019, Article 16(2).

(ICSMS) and the rapid alert system (known as RAPEX) support such cross-border coordination (see pages 104/105).

7.2. Market surveillance processes

Market surveillance authorities need to act and react in a timely manner 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, 5) informing the public (see Figure 15).

Selection of products: data-driven and targeted

Choosing which products to check is a key phase in market surveillance. Implementing checks on too many products is expensive, while focusing on the wrong ones is ineffective. The way products are selected differs for proactive and reactive market surveillance:

- **Proactive market surveillance:** Selection of products builds on market intelligence (e.g. statistics relating to accidents and hazards, consumer complaints), continuous monitoring of developments (e.g. new technologies and product developments) and screening of information (e.g. from other authorities, RAPEX notifications). Proactive market surveillance never stops learning. Experiences from past evaluations offer important insights which guide future activities. The choice of products is planned annually. As a rule of thumb, market surveillance authorities prioritise products produced in large quantities with the potential to cause a serious hazard in terms of human health and safety or to pose other higher risks – and are thus a more likely reason for concern.

- **Reactive market surveillance:** Selection of products is comparatively straightforward, since it is a response to an outside event involving a particular product. Before reacting, however, authorities must verify the complaint, assess whether a product falls within their scope (e.g. directive/regulation) and geographic responsibility – i.e. whether a product was produced, imported, made available, displayed or used for the first time in its area/country. If they are responsible, they are obliged to react. If they are not responsible, they must inform the authority that is.

Sample collection: taking a closer look at suspicious products

The authority takes further action to evaluate product compliance if there is reason to do so. This could be due to an obvious defect or non-compliance, notification from other authorities or suspicion due to a missing or misshaped CE marking. Further action may also be taken if the economic operator fails to provide any information requested, such as the declaration of conformity. In such cases, on-site inspections are followed by physical product checks (e.g. in laboratories).

It is the task of the market surveillance authority to decide how to collect samples, which samples to collect and how many. Taking proportionality into account, the approach is determined on a case-by-case basis and considers the legislation that applies, the type of product, the kind of non-conformity to be assessed and the number of products placed on the market. For legislation covered by ProdSG, German market surveillance authorities generally aim

for 0.5 random samples per 1,000 inhabitants and test around 50,000 products per year. These tests range from checks on formal requirements such as markings to simple on-site safety inspections and extensive laboratory examinations.

Authorities may take samples at various locations, either online or from the manufacturer, importer or distributor directly. In general, officials do not give the economic operator prior warning, so as to reduce the risk that samples are not representative. In addition to taking a product sample, they also collect all legally required documentation, including operating instructions, the declaration of conformity and – where appropriate – test certificates. The economic operator must either provide the information requested or help the market surveillance authority to obtain it. After the authority has taken samples, it is required to preserve the evidence by packaging, sealing and labelling it.

Compliance assessment: formalities first, technical checks second

Once a product sample has arrived for testing or an on-site inspection is underway, the authority can begin to assess a product's compliance. First, the authority checks whether the product is already registered on the ICSMS database – if not, the information is added. This avoids duplicating work should another authority be looking into the same product simultaneously or have already evaluated the case. Second, the authority identifies the responsible economic operator so they can be contacted quickly should further information or corrective measures be required. Third, the authority requests documentation, such as the declaration of conformity.

Following these initial steps, the authority carries out a formal assessment, i.e. it checks administrative requirements such as conformity markings (e.g. CE marking), traceability aspects, accompanying documents (language of user manuals), EU declaration of conformity and technical documentation. If necessary, the formal assessment is followed by a technical assessment, during which the authority checks the contents of the EU declaration of conformity as well as the conformity assessment procedure, i.e. whether essential requirements are met. This is done either by the market surveillance authority itself or through a third-party body (e.g. testing laboratory). Sometimes only visual checks are required, sometimes the examination is conducted by an appointed expert/test laboratory.

If the market surveillance authority finds a non-conforming product, it assesses what risk this non-conformity poses. Risk assessment by the market surveillance authority should not be confused with the manufacturer's risk assessment as part of conformity assessment. The manufacturer carries out a comprehensive assessment of all potential product hazards that require mitigation during product design or production. The authority, on the other hand, evaluates the type and level of a product's risk for human health and safety or other aspects of public interest – with the aim of determining adequate follow-up measures in the event of non-compliance.

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.[68] The method builds on the RAPEX Guidelines[69], which form part of the framework of the General Product Safety Directive.[70] 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 particular case in line with requirements. The general risk assessment methodology has been adapted by the Administrative Cooperation Groups (AdCos, see page 104) for legislation that does not relate to health and safety aspects (e.g. for EMC).

Follow-up measures: proportionate to risk

When market surveillance authorities find that a product is non-compliant and poses a risk to public interests, they implement follow-up measures in line with the relevant legislation. The type of follow-up measure depends on the risk posed by a non-compliant product.

If the non-compliant product does not pose a serious risk, market surveillance authorities first request the economic operator to take appropriate actions within a reasonable time period. These may include:[71]

a. bringing the product into compliance;

b. preventing the product from being made available on the market;

c. withdrawing or recalling the product and alerting the public;

d. destroying the product;

e. affixing to the product warnings of the dangers that it might present;

f. setting prior conditions for making the product available on the market;

g. alerting end-users at risk.

If the economic operator fails to take necessary action, the market surveillance authorities will themselves implement further restrictive measures (e.g. sales bans) and invoke the safeguard clause procedure, should the non-compliance affect more than one EU member country. The safeguard clause procedure ensures that all other national market surveillance authorities are informed about non-compliant products.

The safeguard clause procedure is immediately invoked if a product poses a serious risk. Additionally, market surveillance authorities notify their findings via RAPEX (see pages 104/105).

Sanctions: national law punishes non-compliance

National law is the legal basis for sanctions concerning violations against legislative provisions. For example, breaches of the German Product Safety Act (ProdSG) can attract penalties ranging from 10,000 euros to 100,000 euros, depending on

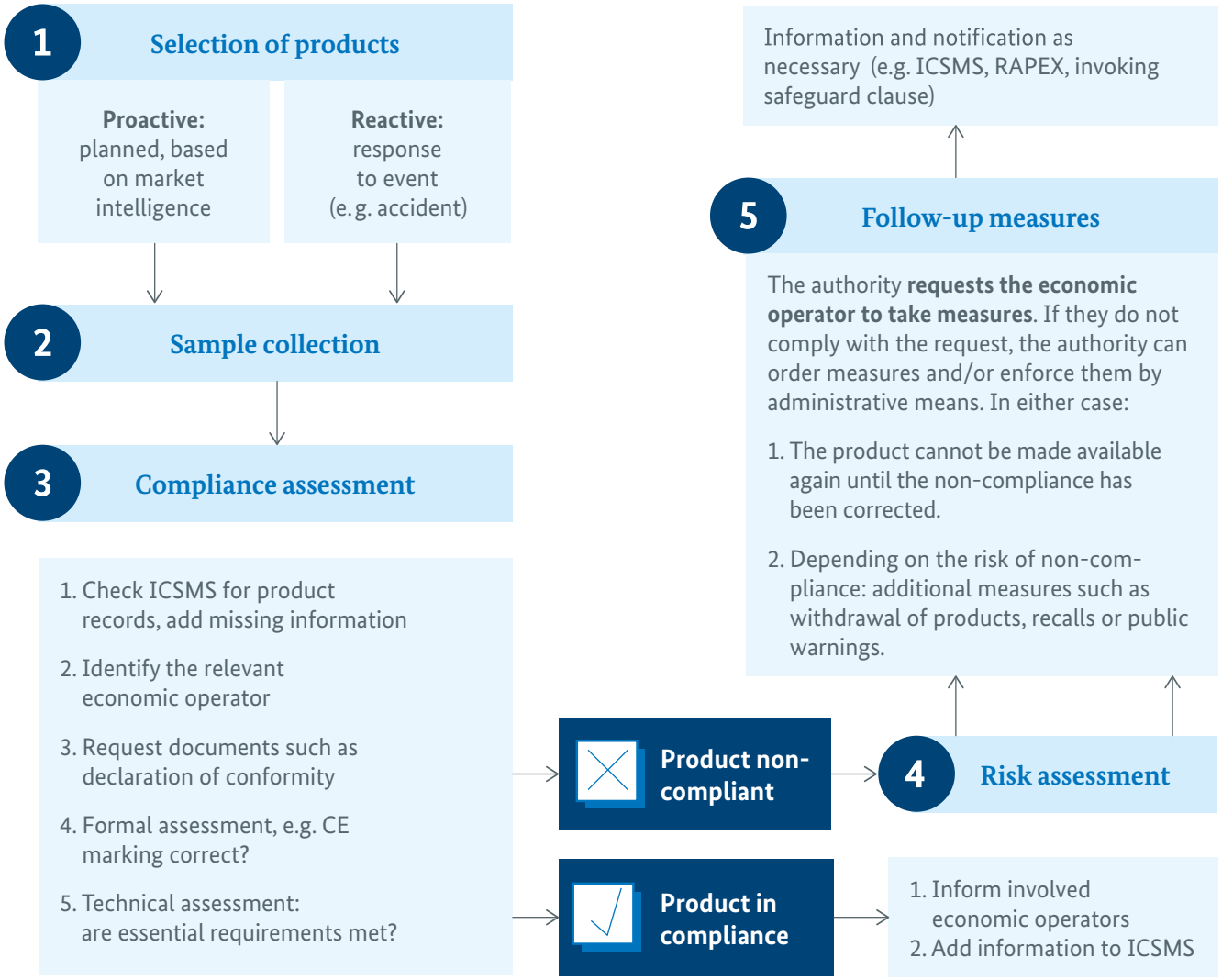
68 See "EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76)", available at http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations/.

69 See Annex to the Guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC, available at https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/Guidelines%20annex_en.pdf.

70 See Directive 2001/95/EC, available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0095&from=DE.

71 This is a shortened and simplified list based on Art. 16(3) of Regulation (EU) 1020/2019.

Figure 15: Simplified steps in EU market surveillance



Source: Own representation based on EU (2017): Good practice for market surveillance, available at https://ec.europa.eu/docsroom/documents/23041.

the seriousness of the non-compliance. Offences include failure to properly inform the relevant authorities, correctly affix conformity markings or provide instructions of use. Certain offences are treated as criminal acts and may be punished with imprisonment. For products covered by the German law on Electromagnetic compatibility, fines can extend to 50,000 euros, depending on the nature of non-compliance.

7.3. Cross-border cooperation in market surveillance

Cross-border cooperation between national market surveillance authorities seeks to minimise overlapping actions and share best practices. Given the size of the EU market, it is crucial that enforcement authorities in Member States cooperate well with each other if they are to remove unsafe or non-compliant products quickly from the market.

Cooperation between Member States takes place at various levels and through various channels.

The new market surveillance Regulation (EU) 2019/1020 established a new European Union Product Compliance Network (EUPCN) as a platform for coordination and cooperation between market surveillance authorities of the Member States and the European Commission. EUPCN further aims to streamline market surveillance practices across the EU. Before the establishment of EUPCN, horizontal coordination between Member States took place within an Expert Group on the Internal Market for Products (IMP-MSG). This group's mission was to develop cooperation mechanisms between Member States – in particular between customs and market surveillance authorities – and to develop measures that optimise the use of resources.

In addition to these official horizontal networks, sectoral discussions take place through informal groups of market surveillance authorities, so-called Administrative Cooperation Groups (AdCos).[72] AdCos meet several times per year (this varies from sector to sector) and comprise appointed representatives from national market surveillance authorities in a given sector. They discuss market surveillance issues in their respective fields to ensure consistent and efficient actions.

"Effective market surveillance never stops learning. That's why the exchange of information and experiences between market surveillance authorities is essential – in particular across borders. Only then authorities are able to keep up with developments in the market and detect dangerous or non-compliant products – before someone gets hurt."

Hans-Georg Niedermeyer, former Head of ZLS

To enhance cooperation between authorities, market surveillance officers set up the Product Safety Forum of Europe (PROSAFE) as a non-profit professional organisation. PROSAFE develops (non-binding) guidelines with detailed information for businesses on how to manage product recalls and other corrective actions. Since 2006, PROSAFE has coordinated several Joint Actions between market surveillance organisations to strengthen the exchange of best practices among its members. These Joint Actions are financially supported by the European Commission.

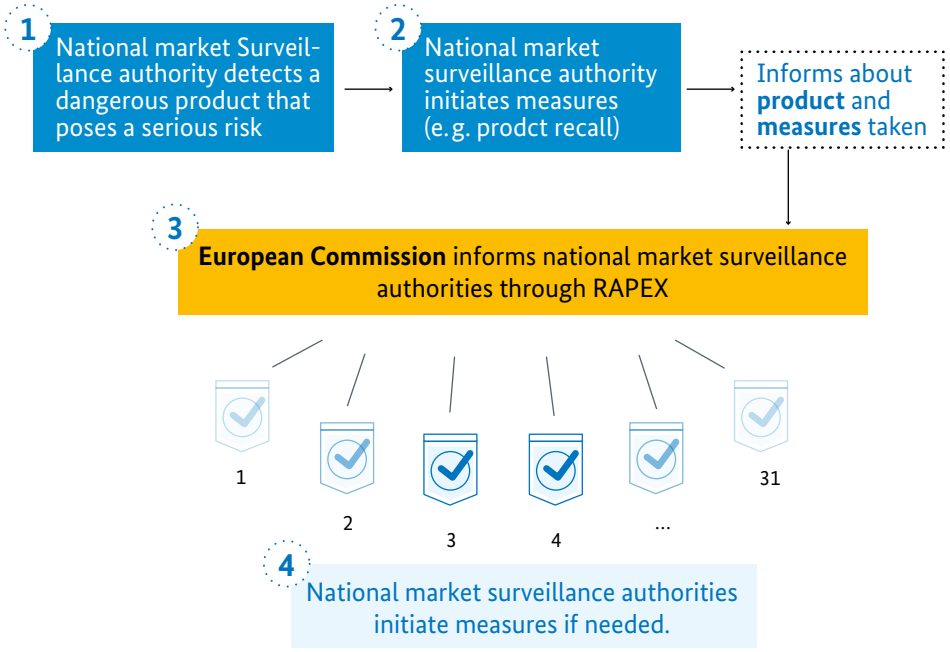
The information backbone for market surveillance: ICSMS

The Information and Communication System on Market Surveillance (ICSMS) provides an IT platform that facilitates communication between market surveillance bodies within the EU. It has an internal area for EU institutions, market surveillance and customs authorities, as well as a public area which is open to everyone.

Member States are encouraged to use ICSMS to make relevant information on product conformity available to other authorities. This includes information on product details (e.g. product type, pictures, customs tariff numbers, serial numbers, place of manufacture), responsible economic operators, applicable Directives and relevant standards, proof of conformity, test results, identified non-compliances, in addition to any measures taken. Although the information stored is comprehensive, ICSMS guarantees the protection of confidential business information and personal data.

72 See https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups/.

Figure 16: Process of informing other bodies about dangerous products (through RAPEX)



Source: Own representation.

Rapid alert for serious risks: RAPEX

If a market surveillance authority identifies a dangerous non-food product, which poses a serious risk that goes beyond its national territory, it informs other Member States through the Rapid Alert System, also known as RAPEX. Thirty-one countries from the EEA region participate in the RAPEX system.

The European Commission controls and coordinates the RAPEX procedure. Every Member State has one national RAPEX contact point that coordinates the exchange of information with the European Commission and other bodies. Once a national authority has identified a dangerous product, the authority initiates a measure (e.g. requests a product recall) and informs the European Commission. The Commission then checks whether the measure taken by a national body complies with EU legislation. It then sends information about the product and measures taken to the other RAPEX contact points (see Figure 16).

The other Member States continuously check RAPEX notifications to see if the relevant product has also been placed on their national market – and take action if needed. They also report back to the Commission on any measures taken.

7.4. Border controls and role of customs authorities

All products are treated alike on the EU single market. EU products as well as products from non-EU countries must comply with EU legislation and be safe. An essential task of border controls is to identify non-conforming or unsafe products before they are placed on the EU market.

Products arriving from a non-EU country must be presented to customs authorities responsible for border controls and undergo a procedure of release for free circulation so that they can be placed on the internal market.

Customs stops a product and market surveillance authorities decide what to do

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 others they are separate. In Germany, customs authorities are not market surveillance authorities.

If customs authorities find a product which might present a risk or does not fulfil the formal requirements (e.g. incorrect CE marking, no German user manual available), they suspend its release and notify the market surveillance authorities. Subsequently, the market surveillance authority has two options:

a. The market surveillance authority takes no action following notification or decides to approve the release of the product. The customs authority can then release it for free circulation. However, such a release for free distribution is not proof of conformity with EU legislation.

b. If the market surveillance authority finds that a suspended product represents a risk or is otherwise non-compliant, it must take measures against the economic operator to prohibit placement of the product on the EU market and requests customs not to release the product for free circulation. In this case, the market surveillance agency requests the customs authority to include a notice indicating that the product is dangerous or non-compliant, e.g. in the commercial invoice accompanying the product.

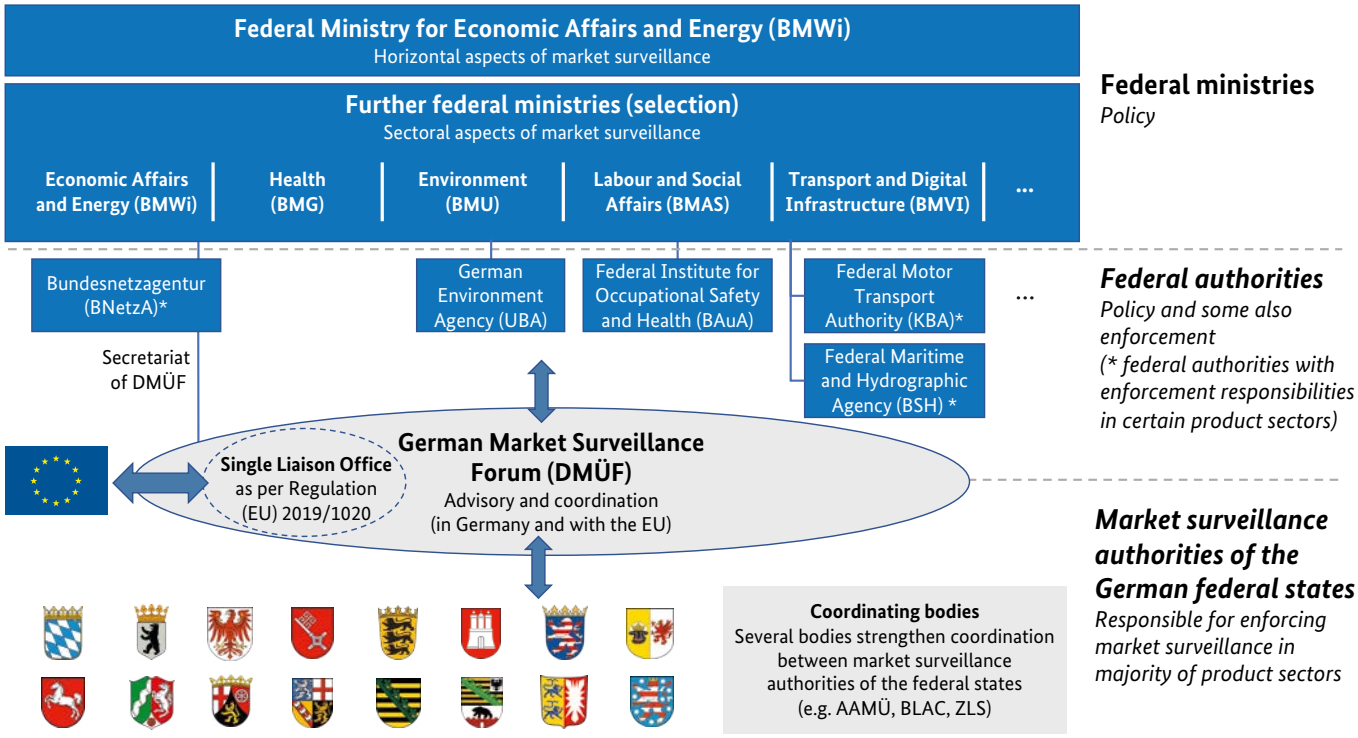
7.5. Implementation of market surveillance in Germany

Within the German Federal Government, the Federal Ministry for Economic Affairs and Energy (BMWi) coordinates cross-sectoral aspects of market surveillance. It also represents Germany in market surveillance issues at European level. Various federal ministries are responsible for the individual product sectors in their competence and the implementation of EU legislation. For example, the Federal Ministry of Health (*Bundesministerium der Gesundheit*, BMG) is responsible for medical devices, and the Federal Ministry for Labour and Social Affairs (*Bundesministerium für Arbeit und Soziales*, BMAS) is responsible for elevators and personal protective equipment (PPE).

In line with Germany's constitutional principle of subsidiarity, the German federal states are responsible for executing federal laws such as ProdSG – which governs product safety and market surveillance for a majority of products in Germany. The federal states, therefore, are generally responsible for enforcing market surveillance. Each state organises its own market surveillance mechanism, taking into account regional circumstances such as the economic structure and existing sectoral priorities.

This means that for market surveillance in most legislative areas, responsibility lies with the market surveillance authorities of the federal states. In a few sectors, federal authorities – not federal states – are responsible for market surveillance. For the Radio Equipment Directive (RED) and the Electromagnetic Compatibility (EMC) Directive, the Bundesnetzagentur (Federal Network Agency, BNetzA) acts as market surveillance authority. Similarly, for automotive vehicles the Federal Motor Transport Authority (Kraftfahrt-Bundesamt, KBA) is responsible (see Table 6).

Figure 17: Overview of key institutions in the German market surveillance system



Source: Own representation.

Table 6: Responsible market surveillance authorities in Germany (not exhaustive)

Areas (selection)	Market surveillance authority
• Medical products • Cosmetics • Toys • Personal protective equipment • Construction products • Pressure vessels and pressurised equipment • Machinery • Elevators • Devices for explosive environments • Batteries • ...	Market surveillance authorities of the federal states (e. g. state-level ministries)
• Transportable pressure equipment	Market surveillance authorities of the federal states Federal Institute for Materials Research and Testing (BAM), Federal Railway Authority (EBA)
• Automotive vehicles	Federal Motor Transport Authority (KBA)
• Radio equipment • Electromagnetic compatibility	Bundesnetzagentur

Source: Based on a visualisation of Bundesnetzagentur (dated 19.03.2020), available at https://www.bundesnetzagentur.de/SharedDocs/Downloads/DE/Sachgebiete/Telekommunikation/Unternehmen_Institutionen/Technik/DMUEF/Geltungsbereich.pdf;jsessionid=BDCBCCF59086D89A491C3FCD3CB165EC?__blob=publicationFile&v=9.

Several institutions strengthen coordination in German market surveillance

In consultation with the federal ministries and the federal states, a German Market Surveillance Forum (*Deutsches Marktüberwachungsforum*, DMÜF) was established at the BMWi in 2018. This forum advises and supports the German Federal Government on matters of market surveillance in the scope of Regulation (EC) No 765/2008 (and Regulation (EU) 1020/2019, as of July 2021). In particular, the DMÜF contributes to developing common legal interpretations across all legal areas concerned with market surveillance and across harmonised legal provisions of the EU (e.g. medical devices, machinery, radio equipment, toys). In addition, the DMÜF discusses and coordinates cross-sectoral issues and current topics, thus intensifying the flow of information at federal state level – for example through expert conferences and workshops. BMWi transferred management of DMÜF to the Bundesnetzagentur.

To ensure uniform market surveillance across the country, the federal states' market surveillance authorities are required to coordinate their activities and exchange information closely. This means, for example, that authorities use the same benchmarks when performing market surveillance activities. As an example of this close cooperation at federal level, the German states have transferred certain tasks relating to coordination of market surveillance from the scope of the German Product Safety Act to the Central Authority of the Federal States for Safety Engineering (ZLS).[73] In the field of medical devices, the federal states established the Central Body of the Länder for Health Protection relating to Medicinal Products and Devices (*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*, ZLG). ZLG regularly updates the quality assurance system for medical device surveillance and assumes responsibility for coordination among the state level market surveillance authorities.

Furthermore, a Working Committee for Market Surveillance (*Arbeitsausschuss Marktüberwachung*, AAMÜ) was established to strengthen coordination across federal states. The Committee is made up of representatives from the relevant state authorities for market surveillance and – as non-voting members – representatives from ZLS, the federal ministries and customs. Their activities include coordination of the national market surveillance strategy, sharing of experiences, development of uniform procedures for market surveillance and maintaining contacts with economic actors and associations. The committee usually meets twice a year.

"As the Bundesnetzagentur, we gladly offer our support to market surveillance authorities around the world that are seeking to develop their market surveillance activities. International cooperation is essential, in particular when it comes to developing market surveillance strategies for products sold online."

Jochen Homann, President, Bundesnetzagentur

73 In addition, ZLS is one of Germany's notifying authorities under EU harmonisation legislation, granting authorisation to notified bodies which perform tasks in conformity assessment.

Information box: When markets shift online, market surveillance has to follow

People are buying and selling a growing number of products online. Today we can order a previously unimaginable variety of products from all over the world while sitting on our sofas. In 2018, e-commerce already accounted for around 20 percent of sales in the EU.[74] This new way of shopping has created multiple challenges for market surveillance. Not only are authorities facing an ever-increasing variety of products they must keep an eye on, they are also finding it increasingly difficult to identify the economic operators responsible – many of whom are based outside the EU. In addition, products are delivered in many individual shipments that are harder to check, for example by customs authorities. The EU and Germany have been adapting to these new realities – with updated legislation, new tools and processes, and enhanced cooperation. With the new Regulation (EU) 1020/2019 on market surveillance and compliance of products, the EU requires for products covered by 18 EU directives and regulations that at least one economic operator in the supply chain must be established in the EU (effective from July 2021 onwards).[75] To account for e-commerce platforms, the regulation introduced a new category of economic operator: the fulfilment service provider. This ensures that authorities can hold at least one economic operator accountable – to recall dangerous products, for example.

Market surveillance authorities invest in new digital tools and processes to support their work in the digital space. For example, the Bundesnetzagentur is working with German and European partners to develop software that searches the web for pictures of products that are the subject of a complaint.[76] This helps authorities to identify which platforms to contact to stop the availability of dangerous or non-compliant products. Germany is also developing tools supported by artificial intelligence that help find potentially dangerous products based on the analysis of online customer reviews. If a certain number of people complain about a product being unsafe, authorities may decide for themselves to take a look. E-commerce also has the potential advantage that buyers can be directly informed by email should a product they have bought be withdrawn or subject to a recall. This approach to tracking and informing customers is not possible in traditional retail – and so opens up new opportunities for authorities. Market surveillance in e-commerce also requires new partnerships. Authorities in Germany have therefore extended the collaboration with online market platforms, so that any identified products can be removed from their websites in a timely manner. This collaboration is not only beneficial to ensuring consumer safety, it is also in the interest of e-commerce platforms whose businesses rely on consumer trust. In response to this, for example, the European Commission facilitated a voluntary commitment by four major e-commerce companies to speed up the removal of dangerous products sold on their platforms.

74 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=E-commerce_statistics#Cross-border_web_sales_within_the_EU_not_fully_exploited_by_enterprises.

75 The applicable regulations and directives can be found in Article 4 (5) of Regulation (EU) 1020/2019. They include for example personal protective equipment, appliances burning gaseous fuels, and equipment and protective systems intended for use in potentially explosive atmospheres.

76 Landesinstitut für Arbeitsgestaltung des Landes Nordrhein-Westfalen, die Servicestelle Chemie aus Tübingen, BAuA.

Case studies: What does market surveillance look like for our case studies?

During market surveillance, authorities check whether products made available on the market are safe and comply with applicable legislation. Which authority is responsible depends on the applicable legislation. If compliance with the Low Voltage Directive (LVD) is in question, the toaster falls within the responsibility of the market surveillance authorities of the German federal states; for the Electromagnetic Compatibility (EMC) Directive, responsibility lies with the Bundesnetzagentur. For example, a smart toaster – i.e. one that can be controlled over a WiFi connection – will be covered by the Radio Equipment Directive (RED) instead of the EMC and LVD, since the essential requirements of the RED also cover EMC and LVD aspects.

Toaster

For the (non-smart) toaster a major concern is its safety – and consequently its compliance with both the Low Voltage Directive (LVD) and its German implementation, the Product Safety Law (ProdSG). So in this example we will focus on market surveillance processes within the scope of the German Product Safety Law.

The German federal states are responsible for implementing market surveillance to ensure a toaster meets product safety requirements. These authorities are divisions of the federal state ministries responsible, such as the Ministry of Labour, Health and Social Affairs of the State of North Rhine-Westphalia or the Bavarian State Ministry for the Environment and Consumer Protection.

The market surveillance authorities may either plan proactive or carry out reactive market surveillance. Reactive market surveillance may be implemented if the authority receives complaints about an unsafe toaster or is informed about non-compliant products through ICSMS. Proactive market surveillance actions are planned measures based on intelligence from accident reports, assessments of RAPEX notifications, complaints from consumers or test reports in consumer magazines. Market surveillance actions take place in line with the focus topics defined in market surveillance strategies (e.g. focusing on electrical appliances traded through e-commerce).

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Project plan for proactive market surveillance action: Before carrying out a proactive market surveillance project for toasters, the authority develops a plan based on the following aspects:

- topic of the project (e.g. temperatures of touchable surfaces of household appliances);
- reason or need for it (e.g. growing number of accident reports);
- objective, target group (e.g. people in households, especially children);
- project participants (e.g. other authorities);
- approach of implementation (e.g. period, number of samples, place to draw samples, etc.);
- estimated personnel and financial resources required.

Using this plan, the market surveillance authority informs other authorities of upcoming projects with a view to exploiting synergies between federal states and avoiding duplication of work.

Sample collection: The market surveillance authority then collects samples of the product. This could be 20 toasters taken from different manufacturers. These toaster samples can be collected at various locations – from e-commerce platforms, supermarkets or from the manufacturer directly – with or without prior notice.

Compliance assessment: First, the authority checks whether any information is available in the ICSMS database and identifies the economic operators responsible for the toaster. Second, the authority carries out a formal assessment: this includes checking the correct CE marking for the toaster, traceability aspects and formal requirements, the EU declaration of conformity and technical documentation. Authorities may have cause for suspicion, for example, if the packaging of an imported toaster does not carry information about the importer. During the compliance assessment, the authority also checks whether the toaster's markings are correct – e.g. whether it has passed the required assessment to carry the GS marking.

Thereafter, the authority decides whether a technical assessment is required. At this point the authority checks whether the essential requirements have been met. A technical assessment may already have been planned as part of the proactive market surveillance project or may be required because initial checks lead authorities to suspect a non-conformity. Sometimes, the authority may order a check by a third-party conformity assessment – these must be notified bodies, GS bodies or any other qualified body.

Several events may be simulated during product testing to provide answers to a range of questions. Will the toaster catch fire if a user toasts slices of bread that are too thick? What happens if the toaster is plugged into a power source supplying too many volts or amperes? Is the toaster likely to tip over and what happens if it does? How hot do the surfaces get that users usually touch?

Measures adopted according to risk: If the authority identifies a non-conforming toaster, it assesses the related risk and takes measures proportionate to the risk. The table below shows examples of risks related to non-compliant toasters and the measures taken by authorities (based on RAPEX notifications). None of the toasters below complied with the LVD essential requirements, in particular those covered by the (voluntary) harmonised standard EN 60335 (Household and similar electrical appliances – Safety).

Table 7: Examples of non-conforming toasters that triggered RAPEX notifications

Risk	Measures taken by market surveil-lance authorities
The metal sides of the toaster become too hot. The user may touch them and receive burns.	Withdrawal of the product from the market.
One side of the toaster becomes too hot and may cause *minor* burns to the user.	Warning to consumers of the risks.
The mechanical resistance of the connection at the main earth terminal is insufficient. As a result, the earth connection could fail.	Withdrawal of the product from the market, recall of the product from end users and destruction of the product.
The product poses a risk of electric shock. Due to inad-equate mechanical strength, the end covers can be pulled away from the toaster's body to expose live components.	Voluntary stop on sales by the importer.
The product poses a risk of electric shock, burns and fire because the appliance is made to resemble a toy and thus appeals to children.	Sales ban ordered by the authorities.
The product poses a risk of electric shock because the heating coil remains live even when the toaster is switched off. There is a risk of electric shock if hands or a conductive utensil are inserted into the toaster and touch the heating coil.	Voluntary withdrawal from the market and recall from consumers by the manufacturer.
The product poses a risk of fire. When loaded with bread specified for normal operation and operated at the rated power input, the toaster catches fire.	Withdrawal from the market and recall from consumers ordered by the authorities.

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Electric Motor

In addition to ensuring safety, a key concern with electric motors is their energy efficiency and hence their compliance with the EU's ecodesign requirements for electric motors – and the German implementation of these through the Ordinance implementing the Law on the Ecodesign of Energy-related Products (EVPGV). The market surveillance authorities of the German federal states are responsible for enforcing market surveillance in line with this legislation in conjunction with the Federal Institute for Materials Research and Testing (BAM). BAM supports the federal state authorities in the development of market surveillance programmes and coordinates an exchange of information – between authorities and with the EU Commission and other EU Member States.

Even though an electric motor is not classed as a consumer product, the market surveillance procedure is largely the same as for the toaster. During assessment of the ecodesign requirements, the authorities also check formal requirements (correct markings, addresses, information available, etc.) and measure the energy efficiency of the electric motor. If a product sample fails to meet energy efficiency requirements – beyond certain tolerance levels – the authority tests three more samples of the same product to ascertain an average value for the motors' energy efficiency.

If the authority identifies a formal or technical non-compliance, it contacts the manufacturer or other available economic operator to correct the deficiency. With regard to ecodesign requirements, authorities rarely issue RAPEX notifications because a non-compliant product will not pose a high risk to people's health or the environment.

Information box 10: Digitalisation of Quality Infrastructure

Digitalisation is continuously generating new products and services. This presents a challenge for current quality infrastructure systems that were developed against the background of more linear processes of product development, production and distribution. Today's products combine both 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 ways of 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 quality infrastructure, starting with the identification of existing standards and specifications for AI suitability and ultimately the

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Information box 10: Digitalisation of Quality Infrastructure (cont.)

realisation and use of smart standards, as this was also carved out in the German Standardization Roadmap on Artificial Intelligence jointly published by DIN, DKE and Federal Ministry for Economic Affairs and Energy. 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 quality infrastructure fit for the digital age. One initiative is the "QI Digital" consortium, jointly founded by BAM, DAkkS, DIN, DKE and PTB and supported by BMWi. These bodies are working together to analyse the different ways emerging technologies affect our quality infrastructure. The goal is to develop a vision of quality infrastructure in the digital age – to address the challenges of digitalisation, but at the same time to 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 the QI Digital consortium is to investigate use cases in order 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 conformity assessment 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, we need a network of safe filling stations. This in turn requires a reliable digital network that uses data from various sensors, makes use of digital twins and deals with interfaces between different 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 quality infrastructure can build trust within such a digital system. This includes the use of digital calibration certificates for filling stations, distributed ledger systems – or blockchain – for verification of information, and smart standards that machines can read automatically.

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- **Quality infrastructure for trust in artificial intelligence: use case on medical products.** Artificial intelligence (AI) has the potential to transform a variety of sectors. Trust is key to all its applications. Quality infrastructure therefore needs to find ways to evaluate autonomous and self-learning systems. QI Digital chose to analyse this with a use case on medical products. In medical diagnostic devices, for example, the use of AI could lead to faster, cheaper and better results than human physicians can achieve. However, current legislation and conformity assessment procedures are ill-equipped to evaluate which AI technologies are reliable, trustworthy and objective. A thorough evaluation of AI methods calls for high quality test and reference data. This is one of the aspects covered by the use case. But the use case also aims to refine our understanding of quality assurance in general – given that the quality of AI not only depends on the measurement of its performance, but also on whether it is explicable and leads to robust results.

Structural foundations for digitalised quality infrastructure

By analysing use cases, experts have identified the challenges and opportunities surrounding the digitalisation of quality infrastructure. However, there are several cross-cutting topics common to these use cases, which conveniently provide the structural foundation for digital quality infrastructure. These include a common data structure for quality infrastructure, a cloud solution for exchange of data, standards that machines can read and execute (i.e. SMART or digital standards), standardised digital twins, and machine-readable digital certificates. Digitalised quality infrastructure also calls for an adapted legislative framework.

- **Linking quality infrastructure to digitalised business processes:** For quality infrastructure to be effective, it must be linked to the processes of companies that are increasingly digitalised. This requires a common data structure of industrial and quality insurance processes and the definition of interfaces.
- **Securing cloud services for the use and exchange of data:** Digitalisation of the quality infrastructure promises efficiency gains compared to traditional approaches. A key requirement is a secure exchange of digital data, for example through cloud services. Different participants in quality infrastructure processes – e.g. companies, conformity assessment bodies, accreditation bodies and market surveillance authorities – can access the information they need from the cloud. Security by design and encryption are key for this to work. In the field of legal metrology, PTB is already working on a European Metrology Cloud.[77]
- **SMART or digital standards that can be read and executed by machines:** Another key step towards the digitalisation of quality infrastructure is the creation of standards that can be read, understood and applied by computers. This is achieved through the creation of common – e.g. XML-based – formats. Machines can then automatically apply the latest standards without human intervention.

77 See https://www.ptb.de/cms/en/research-development/challenges-and-future-prospects/metrology-for-the-digitalization/metrology-cloud.html.

8. Further reading

Please find below a non-exhaustive list of further resources around quality infrastructure.[78]

8.1. International

Ensuring Quality to Gain Access to Global Markets (2019)
A Reform Toolkit

The toolkit was developed with the goal to help to analyse a country's quality infrastructure ecosystem. It compares the demand for quality infrastructure services with their supply, identifies gaps between what is needed and what is being offered in the ecosystem, and addresses those gaps through the development of a roadmap for quality infrastructure reforms.

Available on the websites of PTB (https://www.ptb.de/cms/en/ptb/fachabteilungen/abt9/fb-93/qi-toolkit.html) or the World Bank (https://elibrary.worldbank.org/doi/abs/10.1596/978-1-4648-1372-6).

Quality Policy (2018)
Technical Guide

This guide was developed by the United Nations Industrial Development Organization (UNIDO) and describes guiding principles and elements of a country's quality policy.

Available on the UNIDO website (https://www.unido.org/sites/default/files/files/2018-06/QP_TECHNICAL_GUIDE_08062018_online.pdf).

78 Please note that listing a publication in this chapter does not represent an endorsement.

Economic benefits of standards (2014)

This publication by the International Organization for Standardization (ISO) highlights how standards create value for the organisations that use them and how to calculate the value of standards. Additionally, it provides factsheets of case studies that quantify the benefits of standards for companies of various sectors and countries.

Available on the ISO website (https://www.iso.org/benefits-of-standards-the-iso-materials.html).

Rebooting Quality Infrastructure for a Sustainable Future (2018)

This publication by the United Nations Industrial Development Organization (UNIDO) analyses the contribution of quality infrastructure to the achievement of the UN Sustainable Development Goals (SDGs).

Available on the UNIDO website (https://tii.unido.org/news/rebooting-quality-infrastructure-sustainable-future).

8.2. European Union

The 'Blue Guide' (2016)
on the implementation of EU product rules

The Blue Guide is a publication by the European Commission that gives a comprehensive overview of EU product rules (esp. New Legislative Framework, standardisation, conformity assessment, accreditation, market surveillance). The EU is currently working on an updated version.

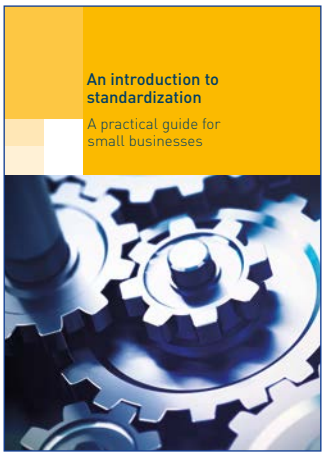
Available on the EU website (https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_de).

8.3. Germany

The Economic Benefits of Standardization (2011)
An update of the study carried out by DIN in 2000

The study analyses and illustrates the effects of standardisation on the German economy.

Available on the DIN website (https://www.din.de/resource/blob/89552/68849fab0eeeaafb56c5a3ffee9959c5/economic-benefits-of-standardization-en-data.pdf).



An introduction to standardization (2016)
A practical guide for small businesses

The guide defines important terms and explains fundamental processes in standardisation at the German, European, and international level.

Available on the DIN website (https://www.din.de/resource/blob/195038/64b75612aae6d6e7341e815becadb5d9/an-introduction-to-standardization-data.pdf).

Overview of key quality infrastructure institutions in Germany

BAM

BAM – Federal Institute for Materials Research and Testing

Key responsibilities

The Federal Institute for Materials Research and Testing (*Bundesanstalt für Materialforschung und -prüfung*, BAM) is a senior scientific and technical federal institute with responsibility to the Federal Ministry for Economic Affairs and Energy. BAM conducts research, undertakes testing and provides advice with the aim of protecting people, the environment and material goods. Working at the forefront of materials science, materials engineering and chemistry, BAM makes a crucial contribution to the technical safety of products and processes and to people's lives in general.

Services

BAM is a partner and service provider for businesses, public authorities and scientific institutions. Focusing on five sectors – energy, infrastructure, environment, materials and analytical sciences – BAM combines research, assessment and consultation in technology and chemistry under one roof. The institution offers services in testing, analysis and the licensing of materials, technical products and machinery. In addition, BAM provides science-based services on safety-related issues, including assessments and expert appraisals, certified reference materials and round robin tests.

BAM's certification body offers services in both regulated and non-regulated sectors. It certifies products and quality systems and carries out inspections as part of required monitoring activities. Testing is generally carried out at BAM's in-house laboratories. Most certifications concern products covered by EU and national legislation. Accordingly, BAM also operates as an EU notified body in the following sectors: transportable pressure equipment, pyrotechnic articles, construction products, equipment and protective systems intended for use in potentially explosive atmospheres and explosives for civil uses.

In addition, BAM participates in international and national standardisation working groups for conformity assessment (DIN, ISO/CASCO). BAM offers consultancy services to legislators, authorities and private enterprises on matters of conformity assessment and of mutual recognition of test results and certification in international trade. BAM also manages the office of the Accreditation Advisory Board (AKB) in line with the German Accreditation Body Act, and coordinates the participation of interested groups in accreditation-related processes.

Brief history

BAM's predecessor was the Prussian Royal Laboratory for Mechanical Testing, founded in 1871. The laboratory conducted mechanical tests on materials, as well as other tests of scientific or public interest. Over the decades that followed, the landscape for material testing institutions in Germany underwent various changes, until in 1954 the State Materials Testing Office and State Chemical Technical Institute were merged to form the Federal Institute for Mechanical and Chemical Materials Testing. Thereafter, BAM increasingly assumed responsibility for official materials testing for the state of Berlin – and later for the whole of Germany.[79] Today, BAM is a centre of excellence for safety in technology and chemistry. It has a workforce of over 1,600 employees and cooperates with universities, technical colleges and research institutes worldwide.

79 https://www.bam.de/Navigation/DE/Ueber-die-BAM/BAM-erleben/Geschichte-der-BAM/geschichte-der-bam.html.

Organisational structure and ownership

BAM is a higher federal authority and an entity of public law. An advisory council supports the definition of its strategic focus. The council comprises experts on safety in technology and chemistry, as well as from business, science and public administration.[80] An agreement on objectives with BMWi defines BAM's strategic orientation. This is set out in the research programme, as well as in BAM internal agreements on objectives.

Funding

BAM is financially independent and receives annual funding from the German Government of approximately 140 million euros. In addition to the fixed budget, BAM funds itself by participating in competitive research funding programmes, such as those run by the German Research Foundation (DFG), the EU and German federal ministries. This competition for research funding ensures BAM's activities are of a high quality.

Work in the European and international context

BAM plays a key role in various European and international networks.[81] By taking part in joint research projects, international co-publications and international scientific exchanges, the know-how which BAM has acquired from decades of experience is also transmitted beyond Germany's borders. The institution collaborates with over 60 countries and engages in international panels – including the International Energy Agency (IEA) and the World Materials Research Institutes Forum. In addition, BAM works with 1,250 national and international standardisation bodies to support the development of international standards.

Current and future topics

BAM focuses on research that is of considerable relevance to the German economy. Research areas include energy, infrastructure, the environment, materials and analytical sciences. In these areas, BAM performs research on topics of future relevance, including additive manufacturing, nanomaterials and green hydrogen. A current focus for BAM is the analysis of the scientific implications of digitalisation. Given the data-intensive nature of today's scientific experiments, BAM's competence centres are researching and analysing data-related aspects of using measuring equipment and sensor networks. In addition, BAM is involved in the QI Digital consortium (see information box 10).

80 https://www.bam.de/_SharedDocs/EN/Downloads/Legal-basics/advisory-council-decree.pdf?__blob=publicationFile (German version only).

81 For information on BAM's international activities, please visit the 'Networks' portal on the BAM website.

Bundesnetzagentur

Bundesnetzagentur – Federal Network Agency

Key responsibilities

The Bundesnetzagentur (Federal Network Agency for Electricity, Gas, Telecommunications, Post and Railway) is an independent higher federal authority. The agency is a German multisector network regulator that promotes sustainable competition and monitors the markets and infrastructure linked to energy, telecommunications, post and railways.[82] The central task of the Bundesnetzagentur is to ensure compliance with the German Telecommunications Act, the Postal Act and the Energy Act, with a view to liberalising and deregulating the respective markets.[83] It serves as Germany's national market surveillance authority for electromagnetic compatibility and radio equipment.

Services

In addition to its regulatory duties, the Bundesnetzagentur performs a variety of tasks across its areas of responsibility. It manages frequencies and phone numbers, for example, issues postal licenses and provides arbitration support in disputes between customers and energy providers. Furthermore, the authority is responsible for implementing the German energy transition. By accelerating planning for new power lines, the Bundesnetzagentur is seeking to safeguard the future availability and affordability of energy in Germany.[84]

The Bundesnetzagentur contributes to consumer protection by monitoring the market and advising citizens on new regulations. As a market surveillance authority, it helps to protect consumers and establishes a framework for fair competition and the free trade of products that fall under the Radio Equipment Directive (RED) or the Electromagnetic Compatibility (EMC) Directive of the EU. In 2019, it checked the compliance of approximately 5,400 products covered by these two directives – 37 percent of which were not in compliance with the legislation.

Brief history

Prior to 1997, the post and telecommunication sectors were covered by two governmental institutions: the Federal Office for Post and Telecommunications and the Federal Ministry of Post and Telecommunications. When the German postal and telecommunications markets were liberalised, responsibilities were handed to the Regulatory Authority for Telecommunications and Post. It acquired its current name in July 2005, when the mandate was extended to include the electricity, gas and railway sectors.

Organisational structure and ownership

The Bundesnetzagentur is an authority within the scope of business of the Federal Ministry for Economic Affairs and Energy (BMWi) and the Federal Ministry of Transport and Digital Infrastructure (*Bundesministerium für Verkehr und Digitale Infrastruktur*, BMVI).[85] Concerning market surveillance, the Federal Network Agency is responsible for the product sectors EMC and Radio and is subject to technical supervision by the BMWi.

82 See BNetzA Imagebroschuere_en.pdf (p.6).

83 See 01 Introduction to BNetzA (PPT).

84 See https://www.bundesnetzagentur.de/DE/Allgemeines/DieBundesnetzagentur/start.html.

85 See 01 Introduction to BNetzA (PPT).

Funding

The Bundesnetzagentur is a tax-funded organisation.[86] Its revenues and expenditures are included in the BMWi departmental budget. In 2019, the agency had overall expenditure of 220 million euros and an administrative income of 75 million euros (e.g. fees and charges).[87]

Work in the European and international context

As part of its efforts to ensure the networking of infrastructure and to promote competition, the Bundesnetzagentur is a member of numerous European and international bodies, e.g. the International Telecommunication Union (ITU), the Independent Regulators Group (IRG) of telecommunications regulators and the Agency for the Cooperation of Energy Regulators (ACER).[88] The agency also supports foreign authorities and other government agencies through its bilateral cooperation.

Current and future topics

In terms of its responsibilities in relation to telecommunications, the Bundesnetzagentur plays a crucial role in the digitalisation of Germany's economy – e.g. expansion of broadband access. The institution acknowledges that although increased competition in the markets strengthens Germany's industrial competitiveness, it also leads to greater complexities. For this reason, the agency facilitates dialogue between consumers and companies to strengthen consumer protection. To ensure the safety of products and other aspects of public interest, the Bundesnetzagentur is increasingly targeting e-commerce platforms when carrying out market surveillance. The objective is to identify platforms through which cheap – and often non-conforming – products are imported into Germany from third countries. In addition to conducting on and off-site inspections, the Bundesnetzagentur also makes anonymous test purchases. It then pools its expertise and lessons learned in reform discussions at the European level to improve market surveillance.

86 See 01 Introduction to BNetzA (PPT).

87 See BNetzA Annual Report 2019: https://www.bundesnetzagentur.de/SharedDocs/Mediathek/Jahresberichte/JB2019.pdf?__blob=publicationFile&v=6 (p. 135).

88 See BNetzA Imagebroschuere_en.pdf.

DAkkS
Deutsche
Akkreditierungsstelle

DAkkS – Germany's National Accreditation Body

Key responsibilities

The national accreditation body of Germany is the *Deutsche Akkreditierungsstelle* (DAkkS). It operates on the basis of EU Regulation 765/2008 and the German Accreditation Body Act (*Akkreditierungsstellengesetz*, AkkStelleG). DAkkS is the sole provider of accreditations in Germany and acts in the public interest.

Services

DAkkS is responsible for the accreditation of conformity assessment bodies – i.e. inspection, verification and certification bodies, and laboratories. In this function, DAkkS assesses, attests and monitors the technical competence of such bodies. Accreditation decisions are made impartially and independently: shareholders have no influence; all clients are treated on an equal footing. In fulfilment of its legal mandate, the core work of DAkkS is authoritative accreditation in Germany in line with German administrative law. The organisation also carries out accreditation work outside the EU.[89] In cooperation with the German Institute for Standardization (DIN), DAkkS assumes specific responsibilities as part of Germany's National TBT Enquiry Point (TBT: technical barriers to trade) and in line with the provisions of the World Trade Organization (WTO).

Brief history

DAkkS began operations in 2010 following the implementation of Regulation (EC) No 765/2008, which mandated EU member states to appoint a single national accreditation body. Previously, Germany's accreditation system had been fragmented, with around 20 different public and private bodies involved in partially overlapping accreditation activities. When DAkkS was formed in 2009, the newly founded private company incorporated a merger of the main private accreditation bodies and the German Calibration Service.[90] The German Government then appointed the newly formed organisation to serve as the national accreditation body. This restructuring meant that DAkkS could build on the existing infrastructure, experience and technical competence of the earlier accreditation bodies.

Organisational structure and ownership

DAkkS was established as a company with limited liability operating on a non-profit basis. It is owned equally by the Federal Republic of Germany (represented by the German Federal Ministry for Economic Affairs and Energy), the federal states (i. e. Bavaria, Hamburg and North Rhine-Westphalia), and the Federation of German Industries (*Bundesverband der Deutschen Industrie*, BDI) – each with a one-third holding in DAkkS shares. Two organisational bodies supervise DAkkS: the three shareholders mentioned above (Shareholder Assembly) and a Supervisory Board with members appointed by the federal gov-

89 https://www.dakks.de/en/content/how-does-accreditation-procedure-work.

90 https://www.dakks.de/en/content/history-and-origins-dakks.

ernment, industry and the federal states. An accreditation committee made up of technical experts takes decisions on the approval, maintenance, suspension and termination of accreditations. An Advisory Board checks that DAkkS conducts its business in an independent and non-discriminatory manner. DAkkS is headquartered in Berlin and has two additional offices in Frankfurt and Braunschweig. It currently employs around 220 people.

Funding

DAkkS covers its costs through fees charged for its activities. The fee structure depends on whether or not the accreditation body's services fall under the category of public authority accreditation in Germany and the European Economic Area. DAkkS carries out most of its activities within the scope of its public authority. Here, accreditation fees charged to conformity assessment bodies are based on the applicable fee schedule determined by the German Federal Ministry for Economic Affairs and Energy. The fee is calculated to cover all personnel and material expenses associated with public authority tasks – without making a profit. A second category of fee is levied if DAkkS operates outside its geographic scope and therefore outside public authority activities. For such non-public authority activities, DAkkS prepares its own fee schedule.[91] For further activities that are not directly related to accreditation or assessment activities, e.g. participation in committees, DAkkS receives funding from the German Government.

Work in the European and international context

DAkkS is embedded in the European and international accreditation systems. The organisation is a full member of the European cooperation for Accreditation (EA), the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). It represents German positions on committees and general assemblies and contributes to the international harmonisation and recognition of accreditation (through multilateral agreements (MLAs) and mutual recognition agreements (MRAs)). In addition, DAkkS is actively involved in technical cooperation activities such as EU twinning projects, which aim to strengthen national accreditation bodies (e.g. in Azerbaijan and Georgia). In addition, DAkkS experts are involved in numerous standardisation committees at national and international level.

Current and future topics

DAkkS continuously updates and refines its accreditation services to meet the changing needs of society and the economy – be that in relation to IT security, data protection, the global supply chain, remote assessments or unmanned aerial vehicles.

91 https://www.dakks.de/en/content/dakks-financing.

DIN

DIN – German Institute for Standardization

Key responsibilities

The German Institute for Standardization (Deutsches Institut für Normung, DIN) is Germany's sole national standards body. It is an independent platform and service provider for standardisation – not a public authority. As a partner of industry, research and society, DIN aims to facilitate global trade, promote innovation, ensure quality and protect people and the environment. DIN is a private non-profit organisation which entered into a public-private partnership with the Federal Republic of Germany upon signing the Standards Agreement in 1975.

Services

DIN coordinates national, European and international projects on standardisation, with the aim of developing standards that reflect the state of the art and are internationally accepted. DIN acts as project manager in this standards development process: DIN staff help ensure that technical committees follow required procedures. DIN also ensures there are no conflicts or overlaps involving standards in Germany – the body's goal is to develop a coherent and uniform collection of standards. In addition to expertise and project management support, DIN provides infrastructure for physical and virtual meetings and databases. It also provides advice on standardisation, builds networks with interested parties and stakeholders and moderates project meetings.

Brief history

DIN can look back at over 100 years of history: its preceding organisation, the Standards Association of German Industry, was founded in 1917. One of its early standardisation achievements is still widely known and in use today. In 1922, it published the DIN 476 standard for paper formats – most people are familiar with the DIN A4 paper format. In 1926, the organisation was renamed as the German Committee for Standardization. After the Second World War, the German Committee for Standardization became a member of the International Organization for Standardization (1951) and one of the founding members of the European Committee for Standardisation (1961). The German Committee for Standardization finally became DIN in 1975. That same year, DIN signed an agreement with the Federal Republic of Germany recognising it as the sole national standards body for Germany.

Organisational structure and ownership

DIN is a private, non-profit association. It is not subordinated to any federal ministry nor any other public authority. The institute is led by a Presidial Board, which lays down the principles of DIN's standardisation policy and makes business and financial decisions. The Presidial Board – which is elected by DIN's members – mainly comprises representatives from the private sector, - but also representatives from the government. The Presidial Board appoints the members of the Executive Board which manages DIN's business affairs, including technical, organisational and commercial matters. The actual standards work is carried out by several standardisation departments.

DIN has two subsidiaries: Beuth Verlag publishes and sells standards – not just German ones, but also European, international and national standards from other countries. DIN Software GmbH manages the maintenance of DIN's databases.

Funding

DIN is mainly financed through revenues from the sale of standards and related services. In 2019, these services amounted to 63 percent of overall revenue. Project funds from the industry represent the next largest source (19 percent), followed by membership fees (10 percent) and project funds from the Government (9 percent).[92] New standards proposals are assessed on the basis of specific need and financial feasibility. Standards are therefore developed only when required by interested parties.

Work in the European and international context

DIN represents Germany's national interests at European and international level through its participation in ISO and CEN committees. It is deeply involved in European standards development. In 2019, for instance, almost 80 percent of new standards published by DIN were European standards. In addition to its work with these standardisation organisations, DIN maintains bilateral ties with key partners around the world. DIN's International Consultation Services support developing and emerging countries in setting up and improving their standardisation systems (e.g. strategy development, optimising standards management processes). This work is funded through third parties.

Current and future topics

Keeping up with technological trends is crucial to the development of state-of-the-art standards. DIN is therefore actively involved in topics of current and future relevance to Germany. For example, DIN works with research projects to ensure their results can be used for standards development. Supported by funding from the German Federal Ministry for Economic Affairs and Energy (BMWi), DIN also engages in research funding programmes on issues of standardisation, e.g. efforts to strengthen innovation and the role of standardisation in the transfer of research and development results. DIN's key areas of focus with regard to emerging economies include Industry 4.0, artificial intelligence, electromobility and smart cities.

92 https://www.din.de/en/din-and-our-partners/din-e-v/financing.

DKE – German Commission for Electrical, Electronic & Information Technologies of DIN and VDE

Key responsibilities

The German Commission for Electrical, Electronic & Information Technologies of DIN and VDE (*Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE*, DKE) is the organisation in Germany responsible for the development of standards and safety specifications in the field of electrotechnology. DKE is covered by the Standards Agreement of the Federal Republic of Germany and is also a division of the Association for Electrical, Electronics & Information Technologies (VDE).

The first standard on electrotechnical safety was created over a hundred years ago. Today, experts working with DKE pool their efforts to draft standards that guarantee the safety of electrotechnical products and installations, and ensure that electricity is generated, distributed and used in a safe and rational way. As the national competence centre for electrotechnical standardisation, DKE is Germany's representative in European (CENELEC and ETSI) and international (IEC) standardisation organisations. DKE works closely with DIN and in line with the German standardisation strategy to represent Germany at European and international level.

Services

As the competence centre for electrotechnical standardisation, DKE provides a platform for electrotechnical standardisation and cooperation between experts – including the project management and institutional support required for standards development.

Brief history

The history of DKE goes back to the world's first electrotechnical association, which was founded by Werner von Siemens and Heinrich von Stephan in 1879. The association's goal was to develop and promote the technical applications of electricity – much like DKE's mission today. In 1893, the electrotechnical association became the Association of German Electrical Engineers (VDE). In 1970, DIN and VDE established DKE and brought in it together all German electrical engineering associations. With the signing of the Standards Agreement between DIN and the Federal Republic of Germany in 1975, DKE is recognised as national standardisation body.

Organisational structure and ownership

Organisational decisions are made within VDE – the association that hosts DKE. An Executive Council is responsible for determining DKE's core principles. It comprises a broad representation of leading personalities from business, science and administration; these are selected from the industry association, for example, as well as from the federal ministries, public media and employer's liability insurance associations. DKE's business organisation is structured into three divisions: technology, production, and external relations and support. The technology division is made up of several sector-specific groups, in which experts work on current and future standardisation topics. The production division provides internal support to the implementation of standardisation projects. The external relations and support division contributes to strengthening DKE's network with national and international experts and governments; it also monitors important standards developments.

Funding

DKE earns 95 percent of its revenues through the sale of standards. The remaining 5 percent stem from a union of sponsors. DKE's work is not supported by public subsidies. Moreover, there are no membership fees and participation in standardisation meetings is free of charge to everyone. This funding structure ensures a high degree of market representation, which in turn increases the relevance of standards developed by DKE.

Work in the European and international context

The German electrotechnical industry generates around 90 percent of its revenues from exports. For this reason, the European and international work of DKE is its key activity: DKE actively represents German interests in European and international standardisation; at technical level DKE holds 37 IEC secretariats, 55 IEC Chairs, 33 CENELEC secretariats and 20 CENELEC Chairs as of 2020. Around 85 percent of European standards in the electrotechnical area are based on IEC standards. In addition to its contribution to international standards development, DKE actively engages in international cooperation with partner countries.

Current and future topics

Given the rapid developments in electrotechnology, new topics for standards development are constantly emerging. The need for standards work may result from discussions among committee members, from standardisation proposals that anyone can submit, or from an EU standardisation request where the European Commission asks CENELEC to prepare a standard. DKE's organisational ties with the market representation of the electrotechnology sector ensure that DKE remains close to technological innovation.

PTB – National Metrology Institute of Germany

Key responsibilities

The National Metrology Institute of Germany (*Physikalisch-Technische Bundesanstalt*, PTB) is a scientific and technical higher federal authority which answers to the Federal Ministry for Economic Affairs and Energy (BMWi). PTB's key responsibility is the realisation and dissemination of the units of measurement. But it is also one of the leading metrological research institutes and a service provider for industry, science and society in general. It derives its legal mandate and activities through 23 laws and ordinances, in particular the German Units and Time Act.

Services

PTB conducts its activities in four interdependent areas: 1) fundamentals of metrology; 2) metrology for the economy; 3) metrology for society; 4) international affairs. The first area includes PTB's core competency – building the foundations of a national metrology system to satisfy current and future requirements. Metrology-related research and development, which makes up around 70 percent of PTB's work, is a crucial task if we are to keep up with emerging technologies. PTB conducts research in cooperation with industry and other institutions. For example, PTB has been actively involved in research aimed at a revision of the SI units, which entered into force on 20 May 2019. The new SI system uses fundamental constants as reference values for all seven base units. This results in more stable and precise units, as they no longer rely on reference objects such as the international prototype of the kilogram. PTB serves the metrology needs of the economy and society by providing various services such as calibration, conformity assessment, advice and information. Through its membership of various national and international bodies, PTB ensures that Germany's metrology system is consistently embedded internationally – and contributes to improving metrology globally. PTB also supports other countries in the development of their quality infrastructures – especially national metrology institutes – through technical cooperation projects commissioned by the German Federal Ministry for Economic Cooperation and Development (*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung*, BMZ).

Brief history

Initial proposals to assure the international unification and perfection of the metric system resulted in the joint signing of the Metre Convention by Germany and 16 other founding members in May 1875. Today, signatories to the treaty number 62 member states and 40 associate states and economies. The convention functioned as an international treaty with the goal of defining internationally valid and uniform measurements and establishing institutions to help achieve this goal. This was the context in which the Imperial Physical Technical Institute (PTR) was founded in 1887. Over half a century later, the institute took the initials PTB (*Physikalisch-Technische Bundesanstalt*) and in 1950 became the national metrological institute of Germany.

Organisational structure and ownership

PTB is an independent institution of public law with responsibility to the Federal Ministry of Economic Affairs and Energy (BMWi). It is governed by a President who is appointed by the President of the Federal Republic of Germany upon nomination by BMWi. An Advisory Board supports the PTB President and the Presidential Board on longer-term strategic decisions.

The organisation is divided into one administrative and ten technical divisions. PTB hosts and chairs a General Assembly on Metrology and Verification that serves as a platform for expert institutions and associations to exchange information on legal metrology. In addition, the German Calibration Service (DKD) is established as a forum at PTB with the aim of supporting uniformity in metrology. Composed of around 400 accredited calibration laboratories and companies, the forum seeks to support the calibration industry with regard to the dissemination of units. This is achieved through information sharing and development of guidelines. PTB has approximately 1,900 employees, 1,500 of them working at its headquarters in Braunschweig. It has two further sites in Berlin.

Funding

PTB received an annual budget from BMWi of around 210 million euros in 2019. In addition, the institute received around 35 million euros in third-party funds raised for research projects – 40 percent of which were raised through EU research programmes. For services provided, including conformity assessments and assessments on behalf of DAkkS, PTB generated an income of 13 million euros in 2019.

Work in the European and international context

PTB actively contributes to global efforts geared to the international harmonisation of metrology. At European level, it is involved in the European Cooperation in Legal Metrology (WELMEC), the European Association of National Metrology Institutes (EURAMET) and the European Platform of Notified Bodies in Legal Metrology (NoBoMet).

Internationally, PTB represents the interests of German industry and consumers in the International Organization of Legal Metrology (OIML). PTB is a signatory to the Mutual Recognition Arrangement of the International Committee for Weights and Measures (CIPM-MRA), which establishes the international equivalence of measurement standards and calibration, and provides for the mutual recognition of measurement certificates issued by the signed national metrology institutes.[93] On behalf of the Federal Ministry for Economic Cooperation and Development (BMZ), PTB carries out bilateral and regional technical cooperation projects to support developing and emerging economies in improving their national quality infrastructures.

Current and future topics

PTB is actively involved in various emerging technologies that are relevant to metrology. One key area is the digitalisation of quality infrastructure. Here, PTB is tasked with ensuring that metrology remains uniform and guarantees accurate and stable measurements. For example, PTB is currently working on machine-readable digital calibration certificates. These are intended to provide secure calibration information that can be processed directly and digitally. PTB is also actively involved in research and development in quantum computing, machine learning and legal metrology involving artificial intelligence.

93 See https://www.bipm.org/en/cipm-mra.

ZLS

ZLS – Central Authority of the Federal States for Safety Engineering

Key responsibilities

The Central Authority of the Federal States for Safety Engineering (*Zentralstelle der Länder für Sicherheitstechnik*, ZLS) fulfils a coordinating and monitoring function in the field of product safety.[94] It is responsible for granting authority to conformity assessment bodies that carry out services relating to the enforcement of national law – e.g. notified bodies in line with EU harmonisation legislation, and bodies responsible for awarding the German GS mark. Furthermore, ZLS has a coordinating function for the market surveillance authorities of the German federal states and in certain cases plays an enforcement role. Its mandate, organisation and financing are set out in an agreement signed in 1993 by the 16 German federal states. ZLS is located at the Bavarian State Ministry for the Environment and Consumer Protection (*Bayerisches Staatsministerium für Umwelt und Verbraucherschutz*, StMUV) in Munich.

Services

The ZLS carries out tasks on behalf of the German federal states in the areas of authorisation, recognition, notification and monitoring of conformity assessment bodies, GS bodies and approved inspection bodies in accordance with several legislative acts (e.g. German Product Safety Act, German Explosives Act). Such an authorisation by ZLS is independent of any accreditation it may have from DAkkS, Germany's national accreditation body – since accreditation is the preferred but not the mandatory approach to proving technical competence.

German states transferred responsibilities to ZLS in order to strengthen federal coordination in market surveillance in line with the German Product Safety Act. Now, for example, if the federal states disagree about a particular market surveillance case, they can assign this case to ZLS for task coordination and execution. In addition, as the key point of contact for market surveillance authorities of other EU members, ZLS plays a part in coordinating activities at EU level.

Brief history

The agreement establishing ZLS was signed in late 1993 by the respective heads of government of the federal states. It entered into force on 1 May 1997. Since then, the agreement has been amended several times. Its coordination role in market surveillance in line with the German Product Safety Act was transferred to ZLS in December 2011 and entered into effect in 2013.

Organisational structure and ownership

ZLS is an organisational unit within the Bavarian State Ministry responsible for technical labour and consumer protection. It is a higher state authority subordinate to the state ministry. In addition to the participation rights of individual states, the responsibilities, organisation and financing of ZLS are laid down in the agreement signed by all the federal states. Guidelines for the activities of ZLS are established by its Advisory Board, on which each federal state has representation.

94 https://www.kan.de/publikationen/kanbrief/marktueberwachung/die-zls-eine-institution-stellt-sich-vor.

Funding

ZLS is partly financed by fees charged for its activities as per the Bavarian Cost Law. Since ZLS also assumes tasks that cannot be specifically attributed to certain payables and debtors, a lump sum is determined during annual budget negotiations and divided between the different German federal states. Each state's contribution is calculated based on its tax income and population size.[95]

Work in the European and international context

Within the framework of the EU's agreements with third countries on the mutual recognition of conformity assessments, ZLS implements activities on behalf of the federal states in the field of recognition or comparable procedures. Furthermore, it represents the German market surveillance authorities responsible for the enforcement of the German Product Safety Act vis-à-vis the EU and its Member States, for example within the Information and Communication System on Market Surveillance (ICSMS). ZLS also processes market surveillance requests based on notifications through the EU's Rapid Exchange of Information System (RAPEX).

Current and future topics

ZLS is continuously involved in expert exchanges to ensure a well-functioning market surveillance system. This includes discussions, for example, on how to ensure the safety of goods bought through online platforms (e-commerce). On account of its role in coordinating market surveillance based on the German Product Safety Act, ZLS is also a member of the German Market Surveillance Forum (DMÜF).

95 www.zls-muenchen.de/wirueberuns/Lesefassung%20ZLS%20Abkommen%20inoffiziell_IhVZ.pdf.

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