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The Basics of Quality Infrastructure for Trade

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Foreword

In an increasingly interconnected and complex world, international trade remains a key engine of growth. International trade can also act as a potentially powerful lever for sustainable development, including in its social and environmental dimensions. However, for the benefits of trade to unfold, the traded products and services need to be safe, for the consumer and for the environment, among others.

When goods are traded internationally, certifications and related procedures need to be complied with both at border and behind-the-border. For this purpose, countries need to have in place specific regulatory and institutional frameworks to assess compliance with standards and regulations. The main mechanisms behind these processes are referred to as the quality infrastructure for trade.

Over the years, the interaction between trade and non-trade objectives has become increasingly complex. Overarching developments such as the green transformation, the rise of artificial intelligence and the quest for gender equity call for updates to existing regulatory and institutional frameworks and pose new challenges for quality infrastructure.

This UNECE publication sheds light on the basics of quality infrastructure, the role it plays in international trade and how it can contribute to the 2030 Agenda for Sustainable Development. The publication also points to some of new and emerging challenges that quality infrastructure will need to address.

Each of the think pieces contained in this publication was developed by a renowned expert in the field of quality infrastructure and builds on the work and accumulated knowledge of the UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP.6).

I invite Governments in the UNECE region and beyond to disseminate this publication and to join UNECE's WP.6 on a journey towards harnessing quality infrastructure as a tool to benefit from trade, while pursuing other legitimate public objectives.

Tatiana Molcean
Under-Secretary-General of the United Nations
Executive Secretary of the United Nations Economic Commission for Europe

Contents

Abbreviations

BIPM	International Bureau of Weights and Measures
CE	Conformité Européenne (EU conformity marking)
CMC	Calibration and measurement capabilities
EC	European Commission
ESG	Environmental, social and governance
EU	European Union
GRS	Gender-responsive standards
IEC	International Electrotechnical Commission
IRC	International regulatory cooperation
ISO	International Organization for Standardization
IT	Information technology
OECD	Organisation for Economic Co-operation and Development
OIML	International Organization of Legal Metrology
SDG	Sustainable Development Goals (of the UN Agenda 2030)
SDO	Standards development organization
SI	*International System of Units* (of the BIPM)
SPS	*Agreement on the Application of Sanitary and Phytosanitary Measures* (of the WTO)
TBT	*Technical Barriers to Trade Agreement* (of the WTO)
TFA	*Trade Facilitation Agreement* (of the WTO)
UN	United Nations
UNDP	United Nations Development Programme
UNECE	United Nations Economic Commission for Europe
US	United States of America
WP.6	Working Party on Regulatory Cooperation and Standardization Policies
WTO	World Trade Organization

Introduction

Quality infrastructure is the unsung hero of trade; it is essential for market access whilst promoting essential regulatory objectives such as safety, quality and sustainability in industrial goods. But it is not well known by the general public. This publication provides a baseline understanding of the different elements of quality infrastructure and some insight as to how this affects trade flows. The main target audience is operators involved in international trade. It can serve as a resource when explaining these requirements to colleagues or supervisors. It can also be useful for experts and government officials already familiar with certain elements of quality infrastructure but seeking more information on the other elements.

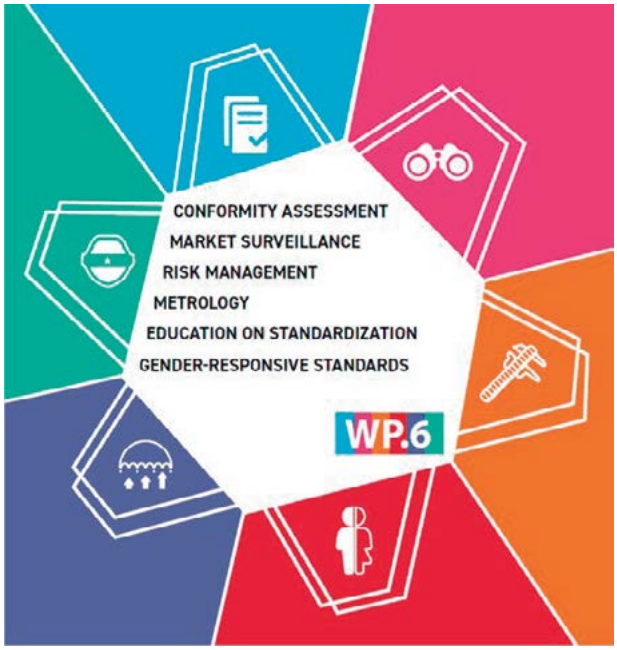
Licit trade does not flow unregulated. Even the simplest of products (like a pencil or a fork) will be subject to regulations before they can be put on the market. Governments have a responsibility vis-à-vis their citizens to ensure that products that are put on the market are safe and will not cause any hazards. For this reason, Governments will establish policy objectives to protect human health and safety, protect the environment, encourage increased circularity, and ensure a certain level of quality. For example, a fork made of lead could have detrimental effects to human health as lead ions could easily leach out from utensils; it is therefore reasonable to expect that Governments will regulate the use of lead (or its non-use) in such utensils.

Most traders will want to create products which do not cause harm to potential consumers. But at the same time, they will want to reduce their costs of production and of sourcing materials in order to increase profit margins. The trade-offs involved between reducing costs and ensuring products are safe can be significant. In a completely unregulated system, consumers will have no assurance that products are safe for consumption; they rely on Governments to provide these base assurances. This is where the elements of quality infrastructure will come in.

> Quality infrastructure is comprised of regulations, structures and bodies (such as accreditation, metrology, standards development bodies) that exist in a country/economy for supporting trade on a fair market to promote safe products and services in a sustainable society.[1]

[1] UNECE WP.6 *Revised Terms of Reference of the Working Party on Regulatory Cooperation and Standardization Policies* (ECE/CTCS/WP.6/2022/11), p. 2.

These legal and regulatory frameworks define technical regulations which are the foundation of market surveillance and conformity assessment, and which are based on metrology and often on international standards. These elements of quality infrastructure comprise the chapters of the first part of this publication along with risk assessment.



Whereas legal and regulatory frameworks address public health, safety and environmental soundness, Governments can interpret these issues broadly depending on their policy priorities. This may include aspects of circular economy in order to ensure that products which are put onto the market have a valid strategy for the entire lifecycle of initial use and subsequent stages of the product. This could also include other aspects of sustainable development such as ensuring that gender considerations are taken into account. Compliance to these regulations is often a greater obstacle to exporters than import duties and taxes given the technical and legal knowledge they require.

In its broadest sense, a technical barrier to trade (TBT) is any regulation or procedure that makes trading with other countries more difficult. Therefore, all of the measures described here could be considered such barriers. Does this mean that country authorities should eliminate these measures and deregulate trade? Of course not. It is recognized that Governments have an obligation to protect human safety and health. This is why under the TBT Agreement of the WTO, it is recognized that there are legitimate policy objectives to protect human health, safety, the environment, etc. However, these policies should not be more trade-restrictive than necessary to fulfil the legitimate objective.[2] This is also why WTO refers to reducing technical barriers and not to eliminating them.

The variations of regulatory priorities from one economy to another may result in very different regulations which is why cooperation is key. Cooperation is necessary between agencies that act at the border within an economy in order to ensure streamlined clearance at the border. Cooperation is also necessary between authorities in different governments in order to ensure that regulations are as harmonized as possible so that a single trader does not have to create different products for different markets (which is why reference to agreed international standards is important).

These aspects are presented in the second half of this publication which concludes with some considerations for the future, linked to the growing digitalization of any products put on the market.

This publication provides some basic understanding of the work which is being developed within the UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP.6). Since

[2] See: https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm#agree1.

1970, this working party and its predecessor have worked on the key aspects of quality infrastructure, providing a neutral forum to convene Governments, standards development organizations, country agencies, private sector and non-governmental agencies to promote cooperation and sharing of experiences.

WP.6 aims to promote regulatory cooperation, standardization policies and activities which contribute towards reducing technical barriers to trade, promoting sustainable development in all its dimensions including, for example, gender equality, climate and environmental protection, circular economy and the adaptation to new technologies.

Further resources exist within WP.6 on these themes including recommendations, e-learning modules, guidance documents. Please see the WP.6 website for more information at: https://unece.org/trade/wp6.

Or contact the secretariat of WP.6 at: regulatory.cooperation@un.org.

Part I:

The basics of quality infrastructure

Standardization

Standards are defined as a:

> "Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context."[3]

Consensus in this definition does not necessarily mean unanimity, but rather reaching the right level of agreement. No one has a veto right in the process of international standardization and it is important to address sustained objections. This process of building agreement speaks to the overall integrity of the results. This definition also underlines that standards are best practices (optimum degree of order) targeting something that will be used over a long period of time and that it will be for a repeated use.

The ISO definition of standard can have a very large application and differs slightly from the definition of the WTO, which concentrates on standards for goods.

Standards are practical tools and processes to guide improvement initiatives at various levels of the quality infrastructure framework. Their essential role is to capture the knowledge regarding usability, quality, safety, performance and other characteristics required by users. They therefore help to ensure that the quality infrastructure provides support and services that assist in facilitating trade collectively, effectively and efficiently.

Standards can contribute to reducing production and transaction costs because there is a rationalization of the processes that then leads to an eventual economy of scale. The uniformity which can be achieved through standards allows for increased market opportunities and the possibility of approaching multiple markets that accept the same standard. Participation within the standardization process – often on a voluntary basis – allows many private sector organizations to have a more competitive positioning. This participation also allows manufacturers and importers to anticipate market developments; progressive companies may see that their internal standards become the basis for an international standard, further enhancing their place in the market. Standards are developed with a comprehensive base of stakeholders who develop the standards in a broad environment, so by the time they make their way into regulations, they have already gained a certain degree of trustworthiness and reliability because they were derived by the very people who will be using them.

Standards serve as a very effective basis for regulation.[4] They are recognized solutions to implement the health and safety requirements of products. Legislations gain acceptance by using standards because

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[3] ISO/IEC Guide 2, 2004, Standardization and related activities – General Vocabulary, paragraph 3.2.

[4] Note from editor: this is reflected in UNECE *Recommendation D on Reference to Standards,* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_D_en.pdf as well as Recommendation B

many of these stakeholders were involved in the development of the standard in the first place. Standards are kept up to date. Within ISO, standards are reviewed every five years to ensure their continued pertinence. This in turn provides assurance to legislators that the standards are regularly maintained and relevant. Standards give access to the latest state of the art requirements that have been developed by the broad stakeholder base.

There are over 160 national standards bodies participating within ISO. Around 75 per cent of these are part of national governments, though there is normally a separation between the regulatory process and the development of standards.

In addition to national standards bodies, the standards development landscape includes consortia, fora, and private standards setting organizations. Stakeholders in standards development are often very well known in an economy, ensuring either formal or informal linkages with other bodies involved in quality infrastructure.

Standardization contributes to legitimizing regulatory objectives and fostering a level playing field. The WTO TBT and SPS agreements both advise the use of internationally agreed standards. Member organizations of ISO have the possibility to declare their adherence to the base principles of the WTO which is then published on the ISO website.

There are six standardization principles which are enshrined in the WTO TBT agreement and are underlined in the work of ISO.

TRANSPERENCY

Transparency can take many forms. The rules of participation are developed jointly with the IEC and are published for anyone to consult. There is also transparency in the time frames for public comments. The current work programmes of all ISO committees are published on the ISO website.

COHERENCE

Coherence across standards organizations working on variations of the same topic is slightly more difficult to support especially in areas linked to technologies. Ideally, organizations should aim to work together and mutually support each other. ISO has established a number of memorandums of understanding to ensure collaboration with other organizations.

on Coordination of Technical Regulations and Standardization, https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_B_en.pdf. Governments can also harmonize their application of standards through mechanisms such as UNECE *Recommendation L on International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practice*, https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_L_en.pdf.

IMPARTIALITY & CONSENSUS

Impartiality and consensus are cornerstones of the ISO process. ISO remains neutral; no matter what the outcome of a discussion, that is what the ISO secretariat supports.

INNOVATION

ISO supports fair competition in the spirit of effectiveness and relevance. International standards further aim to contribute to innovation as well as the implementation of the 2030 Agenda for Sustainable Development.

OPENNESS

ISO works on a basis of openness and does not discriminate anyone who has an interest in the standards development process, though there can be some criteria for participation.

CAPACITY BUILDING

Concerted efforts have been taken for the development dimension, aiming to help developing economies to access knowledge from developed economies.

Moving forward, the COVID 19 pandemic has helped us to rethink how to continue to conduct business. There has been increased reliance on IT infrastructure and remote platforms. This can also help to include more experts from developing economies for whom the travel costs of participation may be prohibitive.

Digitization will expand and strengthen as digital technologies across the supply chain will continue. Standards will continue to play a vital role in underpinning the transformation through fostering trustworthiness in the process, ensuring interoperability of systems and building resilience. Two technologies in particular are being integrated into supply chains and systems to build resilience and to ensure operational sustainability: artificial intelligence and big data.

Social issues such as gender equality and economic empowerment of women through gender-responsive standards will continue to grow in the coming years as more and more standards development bodies embrace this issue and work toward gender mainstreaming.

The UNECE WP.6 provides a forum that brings together the standards developing bodies and the potential government users of the standards. This helps to raise awareness on the essential role of standards within the rest of the quality infrastructure and ensure that standards are properly referenced in regulations whenever possible.

National technical regulations

A technical regulation is defined in the WTO TBT agreement as a:

> "Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."[5]

Even though they can seem similar, technical regulations are different from standards in that their compliance is mandatory while the application of a standard is normally voluntary. Technical regulations are usually adopted at a national level or sometimes a regional level (as is the case with harmonized technical regulations in the EU) and are developed by regulatory bodies such as a public authority. Technical regulations can be used by regulators to achieve different legitimate interests; they can also be applied to a wide range of products. They can, for example be rules on the use of specific symbols to show how these can be recycled, banning the use of certain chemicals, regulating the limits of vitamins that can be used in vitamin supplements or providing safety requirements for toys.

Technical regulations are the basis of the quality infrastructure as they set the mandatory requirements that establishes a foundation to ensure quality and safety in the products we use. They are often adopted with an objective to protect human safety or health, animal and plant life or health, or the environment.

At the same time, even if technical regulations are developed with these legitimate objectives, it is recognized that technical regulations can also interfere with trade. The national aspect of national technical regulations implies that they are only for a specific country or, as in the case of the EU, a region. The consequence of this is that traders may need to adapt their product to market specific regulations depending on where they would like to sell their products. These market specific adjustments can be quite burdensome and costly for a company to adhere to. In this way, national technical regulations can be a barrier to trade.

This is where the WTO TBT agreement comes into place. The agreement tries to strike a balance between the avoidance of any unnecessary obstacles to international trade while at the same time allowing for regulatory autonomy to protect legitimate interests. The TBT agreement does so by establishing a set of

[5] WTO TBT agreement, Annex 1.

principles. Any measure taken that is regulated by the TBT agreement, such as national technical regulations should:

BE NON-DISCRIMINATORY

Any product imported from any Member should not be treated less favourably than products of national origin.

BE TRANSPARENT

WTO Members are obliged to notify and publish all technical regulations and provide sufficient time for dialogue.

BE NECESSARY AND HAVE A LEGITIMATE OBJECTIVE

When national technical regulations are established to protect a legitimate interest, relevant elements of consideration should include available scientific and technical information, possible consequences if the technical regulation is not put in place, the end use of the product and so on. In order to achieve this, regulators need to conduct a proportionality or necessity test – is the measure necessary or has it been taken too far?

TAKE INTO ACCOUNT EXISTING INTERNATIONAL STANDARDS[6]

Regulators should use international standards that are publicly available unless it is deemed inappropriate or ineffective to do so. If there exists an international standard, there has already been international consensus on the appropriate measures that should be taken into consideration.

Notifications of technical regulations under the WTO TBT agreement are done through the WTO system called ePing. It also includes notifications on conformity assessment procedures and standards. The European Union has a similar system and procedure that requires Member States to notify draft national technical regulations to the Commission and fellow Member States on which they can receive comments and reactions; this is accessed through the publicly available database, Technical Regulation Information System (TRIS).

The purpose of such notifications is to reveal how regulators plan to achieve certain policy objectives and what might be the trade implications of the actions that are being taken. Exchanging information on this at an early stage, before technical regulations are finalized, provides trading partners with an opportunity to comment on and initiate a dialogue on upcoming technical regulations. In doing so, it is hoped that this will help to limit the occurrence of unnecessary technical barriers to trade. Furthermore, such exchanges can help to improve the quality of a regulation since more views will be available for the regulator.

National technical regulations are used to drive change and policy objectives. There is an increasing number of regulations, notably to accompany the green transition. For example, there are a multitude of

[6] This is reflected both in UNECE *Recommendation B on Coordination of Technical Regulations and Standardization,* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_B_en.pdf and UNECE *Recommendation C on International Harmonization of Standards and Technical Regulations,* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_C_en.pdf and UNECE *Recommendation D on Reference to Standards,* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_D_en.pdf.

measures proposed under the EU-green deal which require technical regulations, such as the introduction of a digital product passport.

The UNECE WP.6 promotes the harmonization of technical regulations across borders through Common Regulatory Arrangements.[7] These ensure that traders are not faced with unnecessary barriers to entry into new markets and that their products, once compliant to a reasonable set of international standards, will be accepted into multiple markets. This supports the principle of the WTO TBT agreement. The UNECE WP.6 offers a unique, neutral space at the international level to coordinate such cooperation. This is further developed in the chapter on international regulatory cooperation below.

[7] See UNECE *Recommendation L on International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practices.* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_L_en.pdf.

Metrology

Metrology is the science of measurement and its application.

It ensures consistency of measurements. Its origins date back to ancient times, when civilizations often had well-developed measurement procedures, e.g., for the measurement of grains, the building of the pyramids and the construction of aqueducts. Later, as the industrial revolution progressed, the need for metrology increased, for example accurate timing in the field of transport and also to ensure that components manufactured in one country could be used in another.

More recently, metrology has become prominent in other sectors, such as health and life sciences, climate change and environment, food safety, energy and digital transformation. Although metrology touches on nearly all areas within an economy, the basic principles and the base measurements are universal.

SCIENTIFIC METROLOGY

Scientific metrology is the sector of metrology concerned with the realization and dissemination of measurement units, development of new methods of measurement and the realization of measurement standards. Metrological traceability ensures the reliability of measurements, requiring an established calibration hierarchy, i.e., a sequence of calibrations from a measurement standard to the final measuring system.

LEGAL METROLOGY

Legal metrology relates to measurements regulated by statutory (legal) requirements and performed by competent bodies. Legal metrology activities include, for example, the legal control of measuring instruments, metrological supervision, type examination and approval, conformity with approved type, inspection, and verification.

INDUSTRIAL METROLOGY

Industrial metrology refers to the measurements made in the industrial sector. For example, it is used to check the conformity of products and processes as a way of ensuring quality control. This includes concepts such as the metrological traceability of the measurement results as well as specific regulatory aspects.

The main international organizations working in this area are the BIPM and the OIML. The BIPM is the intergovernmental organization through which Member States and Associates act together on matters related to measurement science and measurement standards. Established in 1875, the BIPM represents 108 of the 193 Member States listed by the United Nations, covering around 98 per cent of the world's gross domestic product (GDP). The OIML was established in 1955 and develops model regulations, standards and related documents for use by legal metrology authorities and industry. Member States agree to use the standards/recommendations developed by the OIML as the basis for their national legislation.

Measurement from a variety of perspectives

Legally controlled measurement instruments always concern an instrument dedicated to a specific purpose within a stable environment. The metrological knowledge connected with the instrument is compiled through processes such as "type approval" of the instrument (meaning confirmation by the appropriate authority to ensure that it meets the required specifications). Such instruments include the gas and electricity meters in our homes, and the meters on the pumps at fuel filling stations. In these cases, metrology is dealt with in a specific, standardized way as the instruments and their application are known and regulated.

In areas where measurements are not regulated, it is the market that determines the level of investment in metrology. It is possible to invest a lot of money to make a high-quality product and sell it at a higher price. It might equally be possible to manufacture a lower quality product that is still fit for purpose and acceptable on the market. These areas with unregulated measurements are often driven by innovation, where competitors demonstrate their added value.

The added value might be found in the product itself, or in the processes used to create it – through reducing waste, reducing the number of manufacturing mistakes, reducing the time to market, or using resources more intelligently. All these elements can make a company more competitive in terms of the balance between price versus quality.

Many products will be a blend of these two models (in between legally controlled measurements and unregulated measurements). A product like a car will have hundreds of regulated measurement requirements, but there will also be interoperability aspects of the components, or quality requirements that are not regulated by law. There will, for example, be a set of requirements concerning the safety of a car, which needs to be met in order to put the car on the market. However, many manufacturers will go beyond these basic requirements in order to produce a car that is far safer, and they will emphasize this added value in their marketing.

In industry, many decisions rely on testing – each individual test requires measurements, each of which results in a measurement result. Each measurement result has an associated level of uncertainty. The measurement uncertainties need to be appropriate for the specific application, including the need to satisfy any regulations. Thus, the measurement process and the consequent measurement uncertainties need to be well known and understood.

In all cases, metrology contributes to promoting and sustaining economic development. This is primarily achieved through testing and calibration services, which are typically done at a national level by a national laboratory. In large economies this is often achieved through a network of private metrological testing

and calibration laboratories whose measurement services can be traced back to the national laboratory. Through various mutual recognition agreements in this area, it is also possible to call upon the services of another national laboratory. For example, a company in Sweden traceable to the Swedish national laboratory can provide measurement services to a company in the People's Republic of China, South Africa, or the United States of America. There also exist groupings of national services at regional and international levels. As metrology touches upon so many aspects of international trade, it is impractical to perform all testing at a national level; many of these activities are carried out at a regional level through the cooperation of multiple national laboratories.

Mutual recognition of measurement services through the International Committee for Weights and Measures Mutual Recognition Arrangement (CIPM MRA) is not only based on a paper process, but also on a series of key, scientific comparisons carried out between the national laboratories. The results are peer-reviewed and, when accepted, they support the declaration of calibration and measurement capabilities (CMCs) by the successful participants. An additional prerequisite for publication is for the laboratory to have its quality system reviewed and approved by its regional metrology organization. The CMCs are subject to international peer-review and, upon acceptance, are published in an international and publicly available database maintained by the BIPM: the Key Comparison Database (KCDB).

The pillars of the quality infrastructure are metrology, standardization, accreditation, conformity assessment and market surveillance. These pillars are all inter-linked. Metrology underpins all the other pillars of the quality infrastructure, and in turn many aspects of metrology rely upon the other areas. Metrological laboratories demonstrate their compliance by adhering to documentary standards such as the ISO Committee on Conformity Assessment (ISO/CASCO) ISO/IEC 17025. This standard specifies the general requirements for the competence, impartiality and consistent operation of calibration and testing laboratories. Over 80 000 laboratories world-wide adhere to the standard. ISO/IEC 17025 includes the requirement for measurements to be traceable to the *International System of Units* (SI), whose custodian is the BIPM. A large number of laboratories operating according to ISO/IEC 17025 choose to be accredited by their respective national accreditation bodies. This highlights the strong interconnection between metrology and accreditation.

The level of government investment in metrology, and the consequent depth of capabilities, varies from country to country. Each tries to optimize its system, whilst minimizing its expenditure, to best meet the expectations of its citizens and the needs of the economy. The system described above allows the approval and international recognition process to be applied to laboratories with a wide range of capabilities.

Metrology and developing countries

Metrology is a challenge for national laboratories in developing countries. National metrology laboratories require specific stable conditions, specialized equipment and costly consumables, and require trained and experienced metrologists. In many developing countries, such trained metrologists may be recruited by the private sector, where better salaries can be offered than at the national laboratory.

In the past, developing countries without extensive manufacturing could trade without heavy investment in laboratories for metrological traceability, as they were often trading in basic commodities. However,

even for basic commodities such as grains, it is no longer sufficient to measure just the mass and the humidity levels; it is also necessary to measure contaminants such as the toxin levels in the grain. This requires more demanding testing and enhanced metrological capabilities and infrastructures.

Adding value to the products of developing countries is a cornerstone of economic development. This will often involve pre-packaging of goods which will allow such countries to increase their share of the final sale value of the product. This will involve labelling information such as the mass or the nutritional content; in order to include such elements on a label, it is necessary to perform testing which in turn requires metrology laboratories.

One of the key challenges for economic development is to have these quality infrastructure resources within a country. They do not need to encompass research and development activities, but they must have the testing capabilities allowing them to add value to the goods that they are exporting and enable that value to return to their own countries.

Metrology and the digital challenge

The SI units are based on defining constants and are agreed internationally. These are published in the SI brochure, which also includes decimal multiples and sub-multiples, symbols, and the description of the practical realizations of the units. Making this information available in machine-actionable form will require substantial effort over the coming years. The CMCs in the KCDB and data on time scales published in the BIPM Time Department Database are already available in machine-readable form through dedicated application programming interfaces (APIs).

Improving the fairness of data will enhance future opportunities for leveraging information but ensuring that data are truly interoperable, and reusable will demand significant investment and resources.

The UNECE WP.6 helps to link the organizations working on metrology with the other actors within the quality infrastructure. This facilitates awareness raising and ensuring that the base principles outlined in the UNECE *Recommendation K on Metrological Assurance of Conformity Assessment and Testing*[8] are respected.

[8] See: UNECE *Recommendation K on Metrological Assurance of Conformity Assessment and Testing,* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_K_en.pdf.

Market surveillance

Market surveillance comprises the measures that authorities take to ensure that products comply with the legislation's operational requirements and comply with high levels of protection and fair competition. Market surveillance contributes to ensuring that products do not endanger health, safety or any other aspect of public interest

Basics of market surveillance

Within the product lifecycle, market surveillance will typically come into play when a product is placed on the market, at the sale and usage stages. Prior to that, during the development of a product stage, testing will be necessary. During the manufacturing and introduction on a market stage, product certification, person certification and notification of bodies/markings (like the CE marking) will be necessary. Market surveillance can also be an instrument for post-market control, aiming to curb or correct non-compliant products through actions such as product recall, withdrawal or sanctions. Market surveillance applies to all products placed on the market, whether imported or produced locally. It can also be a complimentary method for combatting non-compliance, dangerous counterfeit and pirated products.[9]

Market surveillance may potentially involve multiple government agencies depending on the economy and the type of product. While a ministry of trade will cover most products (e.g., toys, construction products, precious metals, recreational crafts, measuring instruments); a ministry of agriculture may cover veterinary products and devices; or a ministry of health may cover cosmetics, and drug control; or a ministry of environment may cover chemicals, biocides, detergents, and emissions; while a ministry of transport may cover vehicles, spare parts, marine equipment, and rail equipment. If multiple agencies are involved, they may or may not also have the authority to inspect and clear the types of products under their jurisdiction. Some economies may create an overarching agency responsible for the coordination of all market surveillance activities; some may create a coordinating committee.

[9] Note from editor: This is outlined in UNECE *Recommendation M on Use of Market Surveillance Infrastructure as a Complementary Means to Protect consumers and Users Against Counterfeit Goods,* https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_M_en.pdf.

Market surveillance enforcement plans are based on an analysis of risks. The risk of non-compliance of a toy for a child younger than three years old will likely have greater adverse effects than a hammock. Likewise, the controls and regulations will likely be stricter for such toys compared with hammocks.

Standards and technical regulations are a cornerstone of defining market surveillance requirements. It is in the interest of manufacturers to ensure that their products are compliant in order to be able to put them on the market. Each economy may define their market surveillance requirements differently; so, for a same product, it may be necessary to respond to different standards and technical regulations depending on the markets where the product is intended to be sold.

Market surveillance in the context of a common market

The free movement of goods, as foreseen in the EU, ensures that there are not any hinders from customs or national requirements. The "market surveillance regulation" EU 2019/1020 provides for the harmonization of legislation on products within the common market. This regulation is intended to make it easier for manufacturers who only need to adhere to these common rules and this in turn increases competition and provides benefits to consumers who will have larger access to products which will be safe to use.

According to this regulation, each EU Member State must identify a single liaison office for market surveillance. This office in turn often develops proposals for coordinated positions, submits proposals for a national strategy, represents the Member State in bodies such as the Union Product Compliance Network and administrates the database on market surveillance work of other government agencies. The office may also coordinate the national stakeholders (authorities, business, and consumer organizations) working on market surveillance.

Market surveillance and the digital challenge

Consumers are often purchasing products online and being delivered directly from manufacturers which may not be located in the same economy. This contrasts with traditional supply chains where a distributor within the economy would import a certain quantity of goods at the same time then sell to consumers or to retail shops; the logistics consignments could often be a container full of the same product covered by a same market surveillance regulation. Whereas the explosion of e-commerce is bringing a container full of individual consignment, each containing different products, and each potentially covered by different market surveillance regulations.

In addition, products are becoming increasingly more complex and integrating more technologies. This can bring further complications necessitating the application of multiple regulations for a single product and also addressing continued compliance of the product throughout its lifecycle. (This is further developed in the chapter on "Looking forward".)

Market surveillance contributes to legitimate regulatory objectives. It ensures a high level of protection (to the end user and to the environment) and fair competition. It helps to identify unsafe products. During the COVID pandemic 943 shipments of facemasks – totalling 274 million products – pretending to be personal protective equipment were stopped and checked at the Belgian Border. More than 90 per cent of those did not offer or could not guarantee the level of protection required. There are also new actors who enter the market and propose products but without having performed the safety testing and satisfying other regulatory requirements; market surveillance helps to identify and stop these.

The UNECE WP.6 established in 2003 the Advisory Group on Market Surveillance (MARS) [10] which brings together all players involved in market surveillance (public authorities, manufacturers, retailers, importers, consumers, etc.) to increase transparency and attract attention to the role and responsibilities of public authorities in the chain of control. The MARS is the only international forum for market surveillance authorities to share best practices and keep each other updated on emerging challenges and tools.

[10] See: https://unece.org/trade/wp6/market-surveillance.

Accreditation and conformity assessment

Conformity assessment is the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled. Such requirements can include performance, safety, efficiency, effectiveness, reliability, durability or environmental impacts such as pollution or noise. Conformity assessment includes activities such as testing, inspection, certification and verification.

Conformity assessment procedures are integrated in legislation which defines the requirements with which the products or services – and the related risks that could be posed if the product or service is put on the market – need to comply and how the economic operator can demonstrate this compliance is fulfilled. It is important that legislation be future proof in order to plan for foreseeable evolutions of products and technologies and allow for innovation on the market. Differences in conformity assessment procedures between countries can potentially constitute a technical barrier to trade. Legislators therefore need to take this into consideration.

The conformity assessment itself is not performed by a government body, it is performed by a body that has preferably been accredited. Accreditation acts as a supra layer that guarantees impartiality, confidence in results and competence of the assessors. Accreditation is regulated and is defined as an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonized standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity. Accreditation is a service of public interest and national accreditation bodies act as public authorities and as such are objective and impartial. This should provide confidence in the results.

Accreditation rules in Europe are established by Regulation EC 765/2008 which provides a legal framework for the provision of accreditation services across Europe. It places an obligation on EU Member States to recognize the equivalence of the services delivered by those national accreditation bodies and accept the accreditation certificates they establish, and the attestations issued by the conformity assessment bodies accredited by them.

There is often an understanding that products or services which have a once accredited report or certificate will be accepted everywhere in the world.[11] There are indeed a number of multilateral

[11] Note from editor: See UNECE *Recommendation F on the Creation and Promotion of International Agreements on Conformity Assessment, https://unece.org/DAM/trade/wp6/Recommendations/Rec_F_en.pdf.* The UNECE *Recommendation G on Acceptance of Conformity Assessment Results, https://unece.org/DAM/trade/wp6/Recommendations/Rec_G_en.pdf,* also recommends that Governments develop multilateral agreements for the acceptance of the results of conformity assessment procedures and promote consistent use of harmonized conformity assessments processes used in multilateral mutual recognition agreements.

agreements between accreditation bodies to make this function. However, an accredited report or certificate does not necessarily mean that the results will be accepted by market surveillance authorities worldwide. Under the EU "market surveillance regulation" 2019/1020, it is stipulated that market surveillance authorities need to take due account of test reports and certificates delivered under accreditation for the harmonized sector of products[12]. In other regions in the world, there is no such obligation of mutual recognition of accredited reports or certificates; so, regulators are not bound to accept these.[13]

Key players of the accreditation pillar of quality infrastructure are accreditation bodies and conformity assessment bodies. Conformity assessment bodies can include laboratories (testing, medical exams, calibration), inspection bodies, certification bodies and proficiency testing providers, but also verification bodies. All these bodies verify compliance with the requirements relating to a product, process, service, system, or person. The assessment may be voluntary (requested by bodies that intend to obtain an independent and authoritative third-party declaration of their competence and operative correctness) or mandatory (assessment of conformity of products, services, processes, systems and persons which can be placed on the market after compliance with the reference standards required by laws, directives or regulations).

Conformity assessment is mostly based on standards or schemes at multiple levels: international, regional, national. The assessors performing accreditation of a conformity assessment body need to have competence in the application of these standards or schemes, often of a very technical nature. Assessors need to be specialized in specific areas (i.e., medical devices, personal protective equipment, toys). The accreditation attests that the conformity assessment body or laboratory complies with the requirements established in the standards or technical regulation, in terms of competence, independence and impartiality.

[12] Harmonized sector of products are those products which are subject to common rules across Europe and represent around two-thirds of all industrial products traded in the EU.

[13] Unless there is a trade agreement with the EU tackling mutual recognition in the conformity assessment area.

Accreditation can be done for various activities and products, each based on relevant international standards. Within the EU, these include:

- Management systems certification (ISO/IEC 17021-1)
- Inspection (ISO/IEC 17020)
- Testing and calibration (ISO/IEC 17025)
- Reference material production (ISO 17034)
- Certification of persons (ISO/IEC 17024)
- Validation and verification (ISO/IEC 17029)
- Medical laboratories (ISO 15189)
- Products and services certification (ISO/IEC 17065)
- Proficiency testing providers (ISO/IEC 17043)
- Biobanking (ISO 20837)

Conformity assessment can be performed at three levels. First party assessment is performed by the company itself, self-assessing their conformity. Second party assessment is performed by a different branch within a same company (so there is a relation between the assessor and the assessed). Third party assessment is performed by a different company altogether (so there should be no relation between the assessor and the assessed). Regulators will choose which assessment procedure is appropriate on a product-by-product basis based on the risk, the product, and/or the service.

Conformity assessment and accreditation may save time and money in the regulated area. Manufacturers do not need to test multiple times and can be sure that the resulting product is compliant with regulations, thus saving money. By having confidence in accredited test reports, legislators can also save time and money as they do not need to retest the products. Conformity assessment and accreditation help to establish trust and confidence.

The UNECE WP.6 provides a useful forum where conformity assessment bodies can participate in developing guidance and standards in quality infrastructure and interact with other stakeholders involved in quality infrastructure.

Risk management: ensuring safety without stifling growth

Regulatory frameworks, especially in technical fields where regulations are based on international standards, aim at ensuring the safety of products and systems without stifling growth. Achieving this goal requires dealing with all possible kinds of risks that may arise at all stages of the product lifecycle. Ensuring safety requires addressing these risks throughout all elements of a regulatory framework and quality infrastructure: when developing standards, designing regulations, choosing conformity assessment procedures and planning market surveillance activities. Risk management is not only an essential element of quality infrastructure; quality infrastructure itself is a tool for bringing risks to a tolerable level (in many regulatory frameworks safety is defined as a tolerable level of risk). Applying formal risk management in regulatory systems helps achieve this goal in the most efficient way.

Risk management and standardization

Most international standards deal with risk. From the risk management perspective, they can be grouped into the following categories:

RISK MANAGEMENT STANDARDS

These are standards that describe risk management methodology and tools and provide guidance on their implementation.[14]

SAFETY STANDARDS

There are over 2000 standards in the ISO database on safety and each safety standard includes a section on risk assessment and risk reductions. Such standards provide guidance on applying risk assessment methods by economic operators for ensuring safety of products and systems.

[14] The ISO 31000 series of standards (often cited as one of ISO's best-selling standards) provides principles, a framework and a process for managing risk (see: https://www.iso.org/iso-31000-risk-management.html) whereas IEC 31010 includes a list of risk assessment techniques and tools that can be used in any business or regulatory context.

[15] Until 2015, most of the management system standards (including ISO 9001 on Quality Management, ISO 14000 on environmental management, etc.) did not explicitly include risk-based thinking (apart from ISO 27001 on Information Security Management System, which has always been based on risk management), but they do include it now.

MANAGEMENT SYSTEM STANDARDS

These standards contain requirements for management systems, which are now all based on a risk management process. The evolution of these standards illustrates the growing importance of risk management.[15] Moreover, risk management process serves as a basis for integration of management systems.

ALL STANDARDS

More generally, most standards are developed to address some types of risks. Whatever the standards, it is easy to see the risks it sets out to address, even if the term "risk" is not explicitly mentioned in the standard.

The ISO 31000 series of standards on risk management defines risk as the effect of uncertainty on objectives. Interestingly, there are other ISO standards, mostly covering more technical areas, that have different definitions of risk (e.g., a combination of a severity of harm and probability of occurrence of harm). But all definitions imply the same structure of a risk, which can be described in the following way. A risk includes an event which is uncertain – it may or may not happen (e.g., a car accident) – but if it does happen, it will have an effect on objectives (in terms of money, health, time, etc., depending on whatever is deemed important). The probability of the event happening is defined by risk factors (something known to exist which can give rise to a risk event), also referred to as vulnerabilities, hazards, or risk sources.

To illustrate the concept of risk factors and probability, imagine an unskilled driver (a vulnerability) driving a broken car (a potential hazard) down a bad road (a risk factor) in the rain (a risk source). It does not mean that the driver will necessarily get into an accident; but the probability of an accident happening given these factors will be higher than in the case of an experienced driver driving a new car on a new road in good weather conditions.

Removing or minimizing risk sources is one of the most common ways of dealing with risks, which is an example of a risk mitigation strategy. If we look at the accident case, we can find a lot of standards and regulations that aim at removing or minimizing the impact of each of the risk factors described above. For example, there are standards for road infrastructure, for vehicle safety, or for drivers' competence. These standards in themselves are risk-mitigation tools, but their implementation will be always associated with costs.

There are different risk treatment strategies.

RISK MITIGATION

Risk mitigation is lowering the probability of a risk event or its consequences. It is only one of the available risk treatment strategies, which always comes at a certain cost.

RISK ACCEPTANCE

Risk acceptance is not doing anything to mitigate or avoid the risk, knowing that it is present. In this example, it is possible to decide not to buy insurance for the car. In this case, if there is no accident, the insurance money could be considered saved; but if there is an accident, it will be necessary to pay the consequences (which would be much higher than the insurance costs).

RISK AVOIDANCE

Risk avoidance implies eliminating the activity that contains risks or hazards (not approving autonomous vehicles is an example of risk avoidance). This approach reduces the potential risks (there will be no potential losses), but there will be no benefits of the activity associated with this risk either.

RISK TRANSFER

Risk transfer in this example is the buying of insurance. Another way a risk of an accident can be transferred is outsourcing (taking a taxi).

Risk management methodology helps in choosing an appropriate risk treatment in any given situation. The objective of risk management is not to eliminate risk; it is to get to a tolerable level of risk. This needs to be done in the most efficient way. There is a balance that needs to be drawn between potential losses, the cost of safety measures and the benefit of the activity associated with risk.

In any context, achieving this goal requires a formal risk management process, which will entail establishing the context (objectives, stakeholders, assets), identifying the risks in a timely manner, evaluating the risks (most critical risks receiving the highest priority), choosing a risk treatment strategy, implementing that strategy and contingency planning (in the case that the risk actually occurs).

Risk management in regulation

The UNECE *Recommendation R on Managing Risk in Regulatory Frameworks* [16] recommends that regulatory authorities and other regulatory stakeholders should use the concept of risk to evaluate how balanced regulations are against two extremes: excessive regulation and insufficient regulations that fail to address risk. Safety measures need to be proportionate to risks so that they do not stifle growth and innovation. As shown above, safety measures almost always come at a cost and may potentially create technical barriers to trade. The principle of using risks as the basis for developing regulatory requirements is a prerequisite for ensuring that regulations are proportionate and bring the risk to a tolerable level.

Safety in a regulatory context is defined as “free of unreasonable risk”. This means that the level of risk of a compliant product is considered to be tolerable by regulatory authorities who set the respective requirements. It doesn’t mean, though, that the product is free from risk.

Defining a tolerable level of risk remains a challenging task, especially for products that are new on the market. Several risk management methodologies can assist authorities in regulatory approval of new products. For example, for products that are new on the market where reference to existing regulatory

[16] See: https://unece.org/fileadmin/DAM/trade/wp6/Recommendations/Recommendation_R_en.pdf.

requirements is not possible, a gap analysis can be done against existing (similar) systems/products. If that is not possible, then a detailed risk analysis would need to be done. Often a principle of "as low as reasonably practical" (ALARP) is applied.

Conformity assessment and market surveillance: management of non-compliance risk

Risk management in conformity assessment and market surveillance is essential, inter alia, for choosing appropriate conformity assessment procedures for various products and for setting priorities based on non-compliance risk of a product in market surveillance. Applying predictive risk management tools for targeted market surveillance will help answering the key questions for targeting dangerous non-compliance on the market: how dangerous a non-compliant product is and what is the probability to find a certain product non-compliant on the market.

Non-compliance risk is different from an inherent risk of a product. In many cases, for example, a product non-compliant with a very stringent set of safety requirements can be safer than a product compliant with lower safety requirements when this product is compliant. But such a product can be more dangerous when it is non-compliant than a product with lower regulatory requirements. For example, many cars have sensors and an audible beep can be heard when approaching an object in reverse drive. When these sensors work fine, these cars will be safer than those that don't have such sensors. But if that audible beep stops working, a car with sensors becomes even more dangerous than the car without sensors, because the driver will not expect that it doesn't function. The UNECE *Recommendation S on Applying Predictive Risk Management Tools for Targeted Market Surveillance*[17] was developed to provide guidance on setting priorities in market surveillance based on the evaluation of non-compliance risk of products. It was inspired by the practices developed by WorkSafe (the regulatory authority responsible for electrical equipment in New Zealand) and has been adopted in many countries around the world.

Risk management in international trade

The WTO TFA clearly outlines that we should concentrate efforts on "high-risk consignments and expedite the release of low-risk consignments"[18]; for this, we need to assess the level of risk for each consignment. The WTO TBT also has an underlying notion of risk: "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create."[19] The WTO TBT also outlines that compliance procedures should not be "stricter (…) than is

[17] See: http://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_S_en.pdf.

[18] WTO TFA, article 4.3.

[19] WTO TBT, article 2.2.

necessary to give (…) the adequate confidence that products conform with the applicable technical regulations."[20]

Despite these references within core WTO agreements, article 7.4 of the TFA on risk management remains among those with the lowest implementation score. Implementing comprehensive risk management at the border is a complex endeavour because every consignment will be subject to different non-compliance risks. For example, imagine a consignment of bananas: the ministry of health would probably be interested whether pesticides were used by the producer, but the ministry of agriculture will be interested in dangerous pests in the consignment. For the goods to be released as quickly as possible, all of non-compliance risks should be managed efficiently. If – continuing the bananas example – the ministry of agriculture knows how to do profiling and apply predictive risk management to target suspicious shipments, but the ministry of health stops every shipment to be controlled, efforts of the ministry of agriculture will not have any substantial impact on the overall border compliance time.

The UNECE *Recommendation V on Addressing Product Non-Compliance Risks in International Trade*[21] describes an integrated risk management strategy for border control. It implies bringing all border agencies together to harmonize their criteria for evaluating different non-compliance risks and developing a single, integrated risk management system for border control. It also calls for strengthening the role of import compliance in market surveillance. It proposes a methodology and a reference model on how each border agency can target non-compliance, complemented by a model on how non-compliance targeting systems of individual regulators can be run within an integrated risk management system.

The UNECE WP.6 established the Group of Expert on Risk Management in Regulatory Systems (GRM) in 2010. There are other groups that exist dealing with risk management, but this is the only international group which is specifically dealing with quality of products and services and the relation of risk management to quality infrastructure. The GRM develops recommendations to specifically support a risk management approach to product conformity and provides a forum for the exchange of best practices in relation to the evolving risks.

[20] WTO TBT, Analytical Index, article 5.1.2.

[21] See: https://unece.org/sites/default/files/2023-10/ECE_CTCS_WP.6_2021_05_EN.pdf.

Part II:

Quality infrastructure in the global picture

International regulatory cooperation

There is an increasing amount of national technical regulations being adopted to meet the reality of emerging new technology and to manage global challenges such as climate change. This creates a complex and at times also fragmented regulatory landscape for companies wanting to trade across the globe. With the continuously developing regulatory landscape, there is also a risk of technical barriers to trade emerging.

There is a growing patchwork of regulations around the world which can make trade difficult for stakeholders who are often dependent on well-functioning global value chains. However, there are efforts that Governments can take to ease this burden; one such effort is through the use of international regulatory cooperation (often abbreviated IRC). IRC is usually considered as something that is carried out in formalized trade cooperation, such as within a free-trade agreement, but it can also be conceived as a toolbox of measures to regulate better, more efficiently and limit the occurrence of technical barriers to trade between trading partners.[22]

As described by the OECD, "IRC is often equated with regulatory harmonisation i.e., the complete alignment of regulation across countries. This view on IRC is however incomplete. Policy makers can draw from a wide range of approaches, from unilateral action to multilateral cooperation, from informal dialogues among regulators to supranational rulemaking in international organisations."[23]

IRC is basically a decision between trading partners to promote coordination on regulations that can take place in a variety of ways. These commitments can, in many cases, be carried out in any way that suits the trading partners and the setting can either be formal or informal. One example of a current forum for international regulatory cooperation is the ongoing cooperation within the EU -US Trade and Technology Council.[24]

A study by the National Board of Trade of Sweden[25] demonstrates that there is a full spectrum of regulatory cooperation and many different levels on which international regulatory cooperation can take place and which trading partners can commit, which include:

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[22] Note from editor: This is outlined, for example, in UNECE *Recommendation L on the International Model for Transnational Regulatory Cooperation Based on Good Practice*, https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_L_en.pdf.

[23] OECD, *International Regulatory Co-operation: Adapting rulemaking for an interconnected world,* Policy Brief, April 2020, p. 5.

[24] See: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/eu-us-trade-and-technology-council_en.

[25] National Board of Trade Sweden (2022), An All-Star Approach to Regulatory Cooperation in the Area of Technical Barriers to Trade – Identifying the "best of the best" and how to promote sustainability.

- Information exchange and transparency measures
- Observance of principal trade policy provisions
- Recognition of conformity assessment procedures
- Recognition of results of conformity assessment procedures
- Recognition of (functional) equivalence of technical regulations
- Fully harmonized technical regulations

These different levels of commitment provide economies with various choices on how to approach regulatory cooperation with others. Even the use of more basic forms of international regulatory cooperation – such as the adherence to transparency provisions – can contribute to making regulations better since it involves including others in the regulatory development, taking into account different points of view and objectives and receiving a broader perspective in the rulemaking. The most extensive form of regulatory cooperation is harmonization and coordination on regulations, leading to goods being able to be sold across economies without having to adhere to new regulations or requirements.

International trade is also a strong vector to help achieve the 2030 Agenda for Sustainable Development. IRC provides effective tools to address these objectives while avoiding the introduction of unnecessary barriers to trade. Since IRC promotes coordination and collaboration across economies, it can also enable them to address complex global challenges more efficiently.[26]

The UNECE WP.6 provides a forum to identify and harmonize such regulations that could be coordinated and harmonized through its *Recommendation L*. [27] The common regulatory arrangements (CRA) described in this recommendation bring together the regulatory needs and the existing standards and provide a way forward for harmonization. Several areas are already covered by such CRA; WP.6 will play a key role in the future to help identify further areas and to help facilitate the harmonization of national regulations through its Ad-Hoc Team of Specialists on Standardization and Regulatory Techniques (START) established in 1999.

[26] See National Board of Trade Sweden (2022) Supporting the Green Transition through Regulatory Cooperation within the Trade and Technology Council (TTC), and, The National Board of Trade Sweden (2022) An All-Star Approach to Regulatory Cooperation in the Area of Technical Barriers to Trade – Identifying the "best of the best" and how to promote sustainability.

[27] Op. cit.

Cooperation between government agencies

The cooperation of market surveillance authorities with each other, their cooperation with other quality infrastructure authorities, as well as their cooperation with customs authorities, is one of the key obligations for effective market surveillance.

The Republic of Serbia has prescribed mutual cooperation of competent authorities as an obligation.[28] The objective is to ensure that products placed on the market meet requirements and do not endanger health, safety and other aspects of public interest. This is implemented through numerous development activities, and above all by building an appropriate institutional framework for the implementation of relevant regulations and the coordination of those activities. Building an institutional framework for market surveillance requires the application of appropriate communication and coordination mechanisms within the established rules and principles of market surveillance. This will necessitate identifying the competent authorities, the relevant areas of market surveillance, the appropriate powers and the continuous education for the application of cooperation. This communication and coordination can be facilitated by databases on the activities and measures of market surveillance authorities and systems for exchanging information, including a system for rapid exchange of data on dangerous products.[29] Such a database provides support for harmonizing the activities of market surveillance authorities and unifying data on market surveillance measures.

The cooperation that market surveillance authorities put into place within their jurisdiction include:

- Considering issues related to risks arising from a product
- Monitoring accidents and damage to health suspected to be caused by the risks of dangerous products
- Exchanging records on business entities on previous product non-conformities
- Considering consumer complaints and information received from other authorities, business entities, media and other relevant sources
- Considering risk assessments, including the risk assessments conducted by the authority responsible for customs supervision
- Verifying corrective actions

[28] Law on Market Surveillance (Official Gazette of the Republic of Serbia, No. 92/2011).

[29] Within the Republic of Serbia, this rapid exchange system on dangerous products is the NEPRO platform (see: www.nepro.gov.rs). This platform was established in 2010 based on the Law on General Product Safety (Official Gazette of the Republic of Serbia, No. 41/2009, amended in 2019).

The electronic exchange and storage of information related to issues of market surveillance activities needs to be developed and supported with the framework of the economy's general policy. This will need to integrate matters related to information in relation to non-compliant products.

Knowledge management and keeping abreast of the most recent challenges faced by market surveillance authorities will be an inevitable segment of any kind of cooperation. Joint programs for education and the exchange of experiences will be facilitated by the participation in relevant international bodies, the most pertinent of which is the UNECE WP.6 Advisory Group on Market Surveillance (MARS), the only international body of its kind enabling market surveillance authorities in multiple countries to share experiences and learn of emerging trends.

The cooperation of government institutions that takes place within the established rules and principles of market surveillance for the development of fair competition and the achievement of a high level of consumer protection (i.e., for the achievement of legitimate goals) implies the adoption of a more effective communication strategy for informing business entities and consumers. To achieve this, an exchange of experiences and good practices in the application of a preventive approach and a strategy for informing business entities and consumers should be implemented.

For example, quality infrastructure bodies and market surveillance bodies should provide support to business entities through the creation of informative and educational materials.[30] Such communication may include dissemination of the mutual cooperation established in the application of a risk assessment approach on unsafe products, services and practices with serious and intentional irregularities.

The establishment of a coordination body[31] can also help enhance cooperation and should include representatives of all market surveillance authorities and quality infrastructure authorities. In the Republic

[30] See UNECE *Recommendation I on Education on Standards Related Issues, https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_I_en.pdf.*

[31] This is achieved in the Republic of Serbia with the Product Safety Council, a coordination body in the field of market surveillance established based on the Market Surveillance Law (Official Gazette of the Republic of Serbia, No. 92/2011).

of Serbia, this included a national network of contact points for the exchange of information on dangerous products which is an essential part of the overall coordination of market surveillance, with a clearly established legal basis for the collection, exchange and unification of information between competent authorities, as well as the way of informing the public about dangerous products. Furthermore, special teams are formed for specific issues in the application of certain regulations.

Cooperation and coordination between market surveillance authorities and other relevant national agencies ensure:

- the monitoring and analysis of the implementation of the activities of market surveillance authorities
- the effects of the market surveillance measures taken
- the harmonization of the practices of market surveillance authorities
- the monitoring of communication mechanisms
- the cooperation with the customs surveillance
- the communication with relevant stakeholders with the possibility of giving recommendations in order to apply those mechanisms more effectively, considering reports related to the handling of complaints related to the risks posed by products

This cooperation at a national level is also key to effectively combat counterfeits as outlines in UNECE *Recommendation M on the Use of Market Surveillance Infrastructure as a complementary Means to Protect Consumers and Users Against Counterfeit Goods*.[32] The UNECE WP.6 and it's MARS group are an excellent forum for exchange of such experiences and engaging with other government bodies to identify further best practices in this area.

[32] See: https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_M_en.pdf.

Quality infrastructure and gender

Products can potentially affect women and men differently. This could be because of physical differences, for example reactions resulting from certain chemicals in cleaning products; or the ability to perform in professional uniforms when firefighting suits are oversized for many women; or it could be due to a confluence of sex and gender differences as in the case of the foreseeable misuse of certain technologies like geo-localisation which can be used by stalkers, with women at a greater risk of being stalked. Understanding and recognizing sex and gender differences is a step towards ensuring that products and services can bring the same benefits to women and men.

Foundational to achieving gender-responsive products are the standards and technical regulations used to develop products and used within quality infrastructure (market surveillance, conformity assessment) to ensure the admissibility of the product into the economy. If standards development is not gender responsive it will embed bias in the resulting products.

It is often assumed that standards are neutral and will bring the same results to anyone who uses them, irrespective of their gender. However, studies have shown that standards are very often developed for a reference individual which is based on a Caucasian man aged 25-30, weighing 70 kg.[33] This has resulted in the development of products that are not as effective for women as they are for men. And this has consequences. The World Bank and the WTO underline that women and girls represent half of the potential of the world's population and that reducing the gender gap will promote economic development. [34]

Gender bias is not limited to physical products; it also exists even in highly technical areas. Artificial intelligence systems are based upon hard coding and information that is made available to it. Increasingly there is a concern that machine learning will further perpetuate bias because algorithms are trained with biased datasets thereby reinforcing traditional gendered stereotypes.

[33] Caroline Criado-Perez, *Invisible Women: Exposing Data Bias in a World Designed for Men*, Vintage Publishing, 2020, p. 116.

[34] World Bank and WTO, "Women and Trade: The role of trade in promoting gender equality" 2020.

Gender-responsive standards

WP.6 began working on gender-responsive standards in 2016 and developed the *Recommendation U on Gender-Responsive Standards* which includes a *Declaration on Gender-Responsive Standards and Standards Development*.[35] To date over eighty standards development organizations (SDOs) have signed the *Declaration*, demonstrating their engagement to taking a pro-active approach to gender mainstreaming.

A gender-responsive standard is not a separate standard for different genders, but rather a means of ensuring the impact of the standard is appropriate and provides equitable benefit. The lack of gender responsiveness in standardization has negatively affected women. Standards touch all aspects of our lives; as a result, when standards are not gender responsive, the impact can be simultaneously both pervasive and unidentified. A cross-country analysis from the Standards Council of Canada (SCC) found that across 99 countries, standards are associated with a reduction in unintentional fatalities – for men.[36] Women are not seeing the same benefits from standardization.

Addressing the gender gap in standardization demands concerted actions from all parties. Gender inequality is a systems issue that requires structural changes. It should not be perceived as a women's issue; it is a human rights issue.

Steps to improving gender responsiveness[37]

Standards are often developed within technical committees with experts knowledgeable of the committee's topic. It is within the technical committee's interest to ensure that there is balanced representation and that the resulting standards are gender responsive as this will ensure greater application of the resulting product and that the product will bring the same benefits to everyone.

It is well established that women are under-represented in some highly technical fields (e.g. engineering), as a result it may be difficult to find women experts in the field. However, SDOs can still take action to improve representation. They can encourage women, who are often overlooked for these opportunities, to apply to participate in the standards development process. By intentionally oversampling women to engage more women, they may eventually achieve a more gender-balanced committee. The SDO can also actively seek input from women or women's organizations, particularly as participants from other stakeholder categories will likely already be represented on the technical committee.

In the engagement of women in technical committees, it is important to ensure that meetings are inclusive and do not perpetuate any gendered stereotypes. Women are more likely to be interrupted, even though

[35] See: https://unece.org/DAM/trade/wp6/Recommendations/Rec_U_en.pdf.

[36] Parkouda, M. (2020), *When One Size Does Not Protect All: Understanding why gender matters for standardization*. Ottawa: Standards Council of Canada.

[37] For a more detailed explanation of the steps which can be taken, see: UNECE *Guideline on Developing Gender-Responsive Standards*, 2022.

interruptions can be seen as an indication of dominance and may decrease the likelihood for women to speak up and erode the perceptions of women's expertise.

Regardless of the number of women participating in standards development, the technical committee needs to ensure that the standards that they produce are gender responsive. First, the standards developers should start with the assumption that there are gender differences that will have implications for the standard. Then gather evidence to test if there are indeed differences. This may be difficult as there is often not sex-disaggregated data. By applying a gender lens to standards development this may lead to a reassessment, whereby things that were assumed to be gender neutral are in fact found to have gender implications. Finally, once the gender implications are well understood this must be followed up with action to ensure that any gender difference are taken into consideration and addressed. Even if the evidence is inconclusive or demonstrates that there were no gender implications related to the standard, the analysis will improve performance of the standard since understanding the potential limitations will enable more effective use. It will also improve user confidence by demonstrating that a lack of gender considerations is not an oversight but an informed decision, in those cases.

Gender and current global challenges

There are a number of cross-cutting themes for environmental, social and governance (ESG) concerns which are becoming more urgent than ever. As we move towards more awareness and action in ESG concerns, it becomes even more important to ensure that the resulting standards and their development are gender responsive. Indeed, it is essential to make sure that the standards resulting from ESG concerns will bring equitable benefits to men and women. The UNECE WP.6 Team of Specialists on Gender-Responsive Standards provides a unique platform for the exchange of experience and identifying best practices. This team being under the umbrella of WP.6 also helps to link this work to Government agencies, raising awareness and contributing to mainstream gender throughout the quality infrastructure.

[38] Feldman, A. & Gill, R.D. (2019). "Power dynamics in supreme court oral arguments: the relationship between gender and justice-to-justice interruptions." Justice System Journal 40(3), 173-195.

Quality infrastructure and sustainable development

As the work of the WP.6 Team of Specialists on Gender-Responsive Standards demonstrates, it is possible to integrate specific orientations directly into product standards; in this case, a gender-responsive approach to ensure that the resulting products meets the needs of all (women and men).

In the same way, all Sustainable Development Goals (SDG) targets could potentially be integrated directly into product standards so that the resulting products would ensure that consumption is in line with the objectives of the 2030 Agenda.

From 2017, WP.6 launched a project on standards for the SDGs aiming to document how standards can help to achieve the targets of the SDGs. There has been a great deal of enthusiasm from standards development organizations (SDO) and their technical committees to demonstrate how their standards can help to achieve the SDGs. A series of case studies were put together[39] on practical experience of regulatory authorities, Governments, and local administrations, as well as regional groups of countries, in using standards towards sustainable development and the implementation of the 2030 Agenda. The initial studies were geared towards securing the basic needs of communities like access to drinking water and sanitation, provision of affordable and reliable energy services and safe housing within resilient communities. The SDGs that were chosen to demonstrate both how standards help manage materiality aspects (related to energy and water use) and support the collective aspirations to more resilient and sustainable cities and communities.

Soon after that, all major SDOs have encouraged their standards development teams to identify and communicate, for each standard they develop, the relevant SDGs. This mapping is most often done at the goal level (not the target) as those who are providing the mapping are normally experts on the standard's content – not the SDGs. WP.6 has collaborated with all major SDOs and compiled these mappings to the SDGs into the "Standards 4 SDG" portal.[40]

[39] See: UNECE *Standards for the Sustainable Development Goals* (ECE/TRADE/444), 24 October 2018.

[40] See: https://standards4sdgs.unece.org/

This initiative is complemented by the constant update in some SDOs dedicated websites, showing the standards contributing to achieve the SDGs, particularly in ISO and IEC. Most standards contribute to one or a few SDGs, but only a handful can be linked to multiple SDGs. For example, standards about face masks help to achieve SDG 3 on health, but ISO 14001 on environmental management systems contribute to many more SDGs.

The SDG 9 on "Building resilient infrastructure, promoting inclusive and sustainable industrialization and fostering innovation" is more traditionally linked to standards, with for example close to 20,000 ISO and IEC standards related to SDG 9. But SDOs are progressively addressing other topics, such as circular economy, closely linked to SDG 12 on "Ensuring responsible consumption and production patterns" and SDG 13 on "Taking urgent action to combat climate and its impact".

A number of standards contribute to SDG 12, notably on helping to reduce waste generation (target 12.5). ISO Technical Committee 323 on Circular Economy is considering the whole life cycle of products and improving aspects like recyclability, biodegradability or repairability, specifically ISO 59020 *Measuring and assessing circularity*.

The efforts done by ISO addressing climate action are significant and include a climate action kit and the publication of *Net Zero Guidelines*[41], launched at the United Nations Climate Change Conference (COP27), setting a common understanding of key concepts, principles and claims. Another key action is the resolution to include a sentence on climate change in all certifiable (type A) management system standards[42], which are the most popular and highly implemented in the world (e.g. ISO 9001, ISO 14001 and ISO 27001).

Besides the impact of individual standards, standardization activities play a significant role in SDG 17 on "Strengthening the means of implementation and revitalizing the global partnership for sustainable development". ISO and United Nations Development Programme (UNDP) have signed a landmark Statement of Intent in which they aim to collaborate on the development of an international standard for the SDGs. Such a standard will provide a common basis for documentation and certification, making it easier for organizations and companies to align their efforts and document progress toward the SDGs.

Thousands of standards can be linked to SDGs, but their contributions can vary significantly. The future challenges for the community include linking the standards not only with SDGs, but with specific targets of the SDGs and assess their impact.

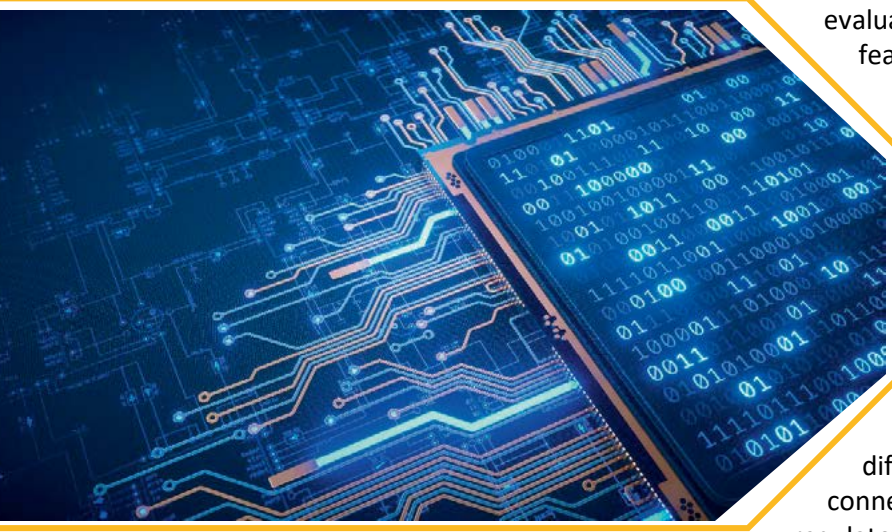
[41] See: https://www.iso.org/ClimateAction.html and the ISO International Workshop Agreement 42:2022 available in several languages at https://www.iso.org/netzero.

[42] ISO Type A standards are basic safety standards covering basic concepts, design principles and general aspects that can be applied to all machinery.

Looking forward: Technical regulation of products with embedded digital technologies[43]

Digital innovation is used widely in industrial products today and can bring great benefits. Not only does digital innovation promote the development of new products but also the unique possibility to update products throughout their lifecycle. Regulatory frameworks have often been established prior to the arrival and implementation of new digital technologies. Products with embedded technologies such as software-based products or products making use of machine learning and artificial intelligence (AI) may represent new challenges that need to be addressed by regulation. For example, certain technologies embedded within products may be connected to central or decentralized systems monitoring and/or controlling real or virtual environments in which these products operate.

This connection with remote systems raises another critical issue from the perspective of technical regulation: the properties of a product may potentially change throughout the product's lifecycle. This means that the product may comply with all regulations at the time it is placed on the market but could subsequently change (for example by software updates) and perhaps change with respect to critical regulatory parameters and become non-compliant.



Moving forward, it will likely be necessary to re-evaluate regulatory techniques (e.g., the feasibility of using standards as a basis of regulation) but also compliance models and introduce a lifecycle perspective to compliance. It will be necessary to move towards a continuous compliance approach, i.e., acknowledging the necessity to address continuous change in both regulation and in the enforcement of legislation such as market surveillance.

Products with embedded technologies differ from traditional non-digital and non-connected industrial products as they also raise regulatory concerns related to privacy, cybersecurity, and resilience, not only product safety. Technologies such as AI seek to reap the greatest benefits of digital

[43] This article is based on the analysis by the National Board of Trade Sweden, "Innovation, AI, Technical Regulation and Trade: Questioning the Invisible Hand in the Digital Economy" of 2023 as well as the UNECE "White paper on the regulatory compliance of products with embedded artificial intelligence or other digital technologies" (ECE/CTCS/WP.6/2023/9), September 2023.

development and innovation; whereas cybersecurity and privacy, for example, seek ways to scope, control and protect data. Finding the balance between these interests while not stifling innovation is key for future technical regulation.

These issues are not product specific and will concern all products with embedded technologies whether these concern medical devices, a cell phone or a refrigerator. Market surveillance has traditionally been product specific (vertical) whereas the technologies embedded in products call for acknowledging horizontal digital parameters. This will require new expertise and a horizontal regulatory collaboration as a multi-disciplinary approach to both identify and address risks, vulnerabilities, cyberthreats and increase operational resilience. Only focusing on an agency-specific (sectoral) approach or only focusing on a technology-specific approach (AI) will risk missing important vulnerabilities (due to lack of regulatory coordination), regulatory fragmentation and potentially create new barriers to trade. It is important to note that the application of AI means many very different use cases which not only present different risk in general but may imply different risk for different users/consumers, which need to be observed in regulation.

Additionally, the technology itself may not be completely transparent which will render traceability, auditability and verification of product properties extremely challenging – this applies for companies and regulators alike. The technologies are still in their nascency which makes regulating them also more difficult. The constant evolution of this type of digitalization results in rapid outdating of any technical regulations that are put into place. This implies that agile forms of governance and flexible regulatory approaches will be necessary. Within quality infrastructure, this will imply a need for new tools related to traceability, auditability, verification (e.g., in conformity assessment and market surveillance for products with embedded digital technologies).

When regulating, it might be necessary to enshrine a human decision-making process in products where the stakes for life and health are particularly high. Likewise, regulations should recognize children's vulnerabilities with respect to products with embedded technologies.

The Basics of Quality Infrastructure for Trade

The Working Party on Regulatory Cooperation and Standardization Policies (WP.6) was founded in the 1970s as a forum for exchange on the harmonization of non-agricultural product regulations. WP.6 aims to promote regulatory cooperation, standardization policies and activities which contribute towards reducing technical barriers to trade, promoting sustainable development in all its dimensions including, for example, gender equality, climate and environmental protection, circular economy and the adaptation to new technologies.

WP.6 is the focal point within the UNECE on quality infrastructure. Quality infrastructure is comprised of regulations, structures, and bodies (such as accreditation, metrology, standards development bodies) that exist in a country/economy for supporting trade on a fair market to promote safe products and services in a sustainable society. The WP.6 subgroups allow stakeholders to work together to develop recommendations and exchange on best practices: the Advisory Group on Market Surveillance (MARS), the Group of Experts on Risk Management in Regulatory Systems (GRM), and the Ad-Hoc Team of Specialists on Standardization and Regulatory Techniques (START).

This work is hosted under the UNECE Market Access Section within the UNECE Economic Cooperation and Trade Division (ECTD). The ECTD assists member States with economic integration and in promoting and enabling a better policy, financial and regulatory environment. These support an inclusive and sustainable post-COVID-19 recovery, a transition to a more circular economy, e.g. through the promotion of gender-responsive standards and through digital and green transformations.

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