

5 December 2019

(19-8381)

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**Committee on Technical Barriers to Trade** 

## THEMATIC SESSION ON CONFORMITY ASSESSMENT PROCEDURES: NATIONAL QUALITY INFRASTRUCTURE <sup>1</sup>

12 NOVEMBER 2019, 15:00-18:00 - 13 NOVEMBER 2019, 10:00-13:00

Moderators' Report<sup>2</sup>

The Moderator of the Thematic Session on Conformity Assessment Procedures: National Quality Infrastructure delivered this Report at the WTO TBT Committee's meeting of 13-15 November 2019.

At the Eighth Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with regular meetings of the Committee, and to hold a session on conformity assessment procedures (CAP) in November 2019 with a focus on National Quality Infrastructure (NQI).<sup>3</sup> The programme for the thematic session is contained in the Annex of this report. The presentations summarized below are available through the WTO website.<sup>4</sup>

Guiding questions:5

- What approaches exist for the development of NQI, including metrology, standardization, conformity assessment and accreditation?
- How can Members encourage the use of NQI by their regulators, in order to avoid unnecessary barriers to trade?

## Panel 1: Accreditation

1.1. **Mrs. Konny Sagala**<sup>6</sup> (Indonesia) provided a presentation on Indonesia's experience on the use of accreditation as a basis for conformity assessment acceptance. She stressed that accreditation is an important tool for Indonesia to prove the confidence of conformity assessment results in facilitating trade, both domestically and internationally. Mrs. Sagala described Indonesia's system for standardization (derived from Act number 20 of 2014). She noted that accreditation is a pre-requisite requirement for the recognition of compliance of a regulated product with Indonesia faced a number of challenges, including: (i) the lack of acceptance of the conformity assessment results under the framework of IAF ILAC MRA; and (ii) the fact that some private standards do not recognize accreditation under the framework of IAF ILAC MRA. It was important, she stressed, that WTO Members take into account accreditation. In this regard, accreditation under the framework of IAF ILAC MRA plays an important role in trade facilitation; hence, it was important that WTO Members consider the use of this MRA/MLA for the acceptance of products' conformity assessment results.

<sup>&</sup>lt;sup>1</sup> The final programme was circulated as G/TBT/GEN/272. It is also in Annex I of this document.

<sup>&</sup>lt;sup>2</sup> Mr. BI Zhonglin (China) and Ms Lorena Rivera (Colombia). This Report is provided on the Moderators' own responsibility.

<sup>&</sup>lt;sup>3</sup> <u>G/TBT/41</u>, para. 8.2.a.iv, footnote 298.

<sup>&</sup>lt;sup>4</sup> https://www.wto.org/english/tratop e/tbt e/thematic session cap 121119 e.htm.

<sup>&</sup>lt;sup>5</sup> <u>G/TBT/41</u>, para. 4.17.c.iv.

<sup>&</sup>lt;sup>6</sup> Director of Implementation System for Standard and Conformity Assessment, BSN.

1.2. **Mr. Andreas Steinhorst<sup>7</sup>** (European Union) provided an overview of the European system for accreditation – as part of a national quality infrastructure. He stressed, at the outset, that products benefiting from the free movement of goods within the EU need to fulfil requirements providing a high level of protection of public interests, including in areas such as health and safety – as well as protection of the environment. The European Accreditation (EA) System, based on Regulation (EC) No 765/2008 on Accreditation, is premised – among other things – on the principle of <u>one</u> national accreditation body per country and non-competition between national accreditation bodies. As such it strengthens the use of accreditation in the EU as the last level in the conformity assessment chain and places an obligation on EU member States to accept results issued by the conformity assessment bodies accredited by any of the EA MLA signatories. In the discussion, it was noted that accreditation is important for confidence in international trade. In the case of the EU, regulators accept conformity assessment results from bodies accredited by an ILAC or IAF MRA/MLA signatory if there is a government-to-government MRA or trade agreement in place which would take recourse to the ILAC and IAF agreements and provide for enhanced cooperation between the accreditors of the parties.

1.3. **Eng. Hany El-Desouki**<sup>8</sup> (Egypt) provided an overview of the Egyptian Accreditation Council (EGAC). The EGAC was established in 2008 and granted full independence as the sole accreditation body of Egypt; it was noted that international recognition by ILAC and IAF had been achieved, *inter alia*, for testing and calibration as well as medical laboratories, inspection bodies, certification bodies for management systems, product and personnel besides proficiency testing providers. EGAC also has several significant partnerships, including with the EA and the ISO. Egypt's national quality infrastructure was also described.

# Panel 2: Metrology

1.4. **Mr. Andy Henson**<sup>9</sup> (International Bureau of Weights and Measures (BIPM)) provided an overview of a common international approach to Quality Infrastructure (QI) from the perspective of the *Bureau International des Poids et Mesures* (BIPM). The BIPM, it was explained, is the intergovernmental organization through which countries act together on matters related to measurement science, and measurement standards. Mr Henson spoke about recent developments on QI in particular, and emphasized the new definition of "Quality Infrastructure"<sup>10</sup> that had been developed by a number of organizations in 2017, and the launch, in November 2018, of the International Network on Quality Infrastructure (INetQI).<sup>11</sup> Mr Henson stressed that in the broader context of QI, metrology is essential for supporting innovation, conformity assessment activities and consumer protection, as well as the work of regulators. Sound measurements are achieved by ensuring metrological traceability to internationally agreed standards with the appropriate measurement uncertainty.

## Panel 3: Standardization

1.5. **Ms Yukiko Kotani**<sup>12</sup> (Japan) gave an overview of Japan's Quality Infrastructure. She explained that in 2014 a standardization programme for new market creation had been launched. It had been designed by the Ministry of Economy, Trade and Industry to help companies develop standards to promote innovative products or technologies. She stressed that it was not intended to replace the current system but rather to give companies the alternative path to make standards. An example of how an SME could use this system was described. The benefits, it was noted, were in the system's practicality – it was hoped that 100 standards would be developed through this new programme in 2020.

1.6. **Ms Leslie McDermott**<sup>13</sup> (United States) gave an overview of standardization in the context of the US National Quality Infrastructure. She stressed that, compared to many other countries, the US system is "bottom up" – i.e., standards *users* drive standardization activities. She said that there are different tools for the development of globally relevant standards, ranging from "one-country-

<sup>&</sup>lt;sup>7</sup> Executive Secretary, European co-operation for Accreditation.

<sup>&</sup>lt;sup>8</sup> Executive Director, Egyptian Accreditation Council.

<sup>&</sup>lt;sup>9</sup> Director of International Liaison and Communication Department, BIPM.

<sup>&</sup>lt;sup>10</sup> <u>https://www.inetqi.net/documents/quality-infrastructure/</u>.

<sup>&</sup>lt;sup>11</sup> The following 12 international organizations are part of INetQI: BIPM, OIML, ILAC, IAF, ISO, IEC, ITU, ITC, UNIDO, UNECE, WBG and WTO.

<sup>&</sup>lt;sup>12</sup> Japanese Standards Association Group.

<sup>&</sup>lt;sup>13</sup> Director, International Development, American National Standards Institute (ANSI).

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one-vote" based on national participation (e.g., ISO, IEC); direct participation (e.g., ASTM, ASME); and, consortia driven standards. All of these types of standards are applied in the US market, with users selecting the tool that best fits their needs. In the US view, standards need to meet societal and market needs and not be developed to act as barriers to trade. Ms McDermott stressed that the US system endorses the principles developed by the TBT Committee on international standards, and ANSI accreditation of standards developers reflects these principles. Essentially, the US system is a public-private partnership. Its activities are a mix of government (regulatory programmes) and private sector (market-based programmes). As such the system is flexible, supports a broad range of stakeholders and is well positioned to address emerging priorities and new technologies.

1.7. **Mr. Gonçalo Ascensão**<sup>14</sup> (European Union) gave an overview of the role of standards in quality infrastructure in the European Union. Mr. Ascensão said that the network of CEN & CENELEC includes more than 200 thousand experts and covers several business sectors. Many topics are covered by this work, including environment and smart technologies. He stressed that standards developed by CEN and CENELEC: (i) are based on the national delegation principle; (ii) represent a consensus among all interested parties, including industry & SMEs and societal stakeholders; (iii) are voluntary; (iv) are developed by independent organizations clearly distinct from authorities; and, (v) are in compliance with the TBT Agreement. He recalled that the European standardization model meant that standards are identical across member States, and that there is an obligation to withdraw conflicting national standards. There are about 4,000 harmonized standards listed in the Official Journal of the European Union. The ultimate goal – it was stressed – is to have identical European and international standards. To this effect, 33% of all CEN standards are identical to those of the IEC (with an additional 6% based on those of the IEC).

## **Panel 4: Conformity Assessment Procedures**

1.8. Mr. Adam Dubas<sup>15</sup> (New Zealand) provided an overview on the use of the "regulatory stewardship approach" underpinning how New Zealand manages and develops its National Quality Infrastructure (NQI) and its regulatory systems. He explained that a "regulatory stewardship approach" encapsulates ways to "look after" a regulatory system in terms of: (i) using a whole-ofsystem, collaborative approach; (ii) monitoring and regularly reviewing regulatory systems; (iii) carrying out robust analysis for any regulatory change and supporting its implementation; and (iv) using Good Regulatory Practice (GRP). The ultimate end result of applying such an approach, he said, are optimal regulations that better cater for the wellbeing of New Zealand's population. This also carries a second beneficial consequence: the reduction of regulations constituting unnecessary barriers to trade. Mr. Dubas also illustrated the benefits of using this approach with a case study on how using this approach for reviewing its "conformance infrastructure" led to the development of New Zealand's "Conformance System Strategy"<sup>16</sup>, which is based on four focus areas: organisational performance (more coordination among NQI bodies); regulatory guality and practice (using GRP for CAPs); partnerships for skills and value (use technologies and more NQI workforce training); and international connections (more CAP international cooperation). Ultimately, he concluded, this work demonstrated New Zealand's commitment to the three internationally recognized categories of GRP: (i) internal government coordination of rulemaking activity; (ii) regulatory impact assessment (RIA); and (iii) public consultation mechanisms.

1.9. **Ms Jennifer Evans**<sup>17</sup> (Australia) presented a case study for illustrating the way Australia successfully matches CAPs with NQI capacity. In 2002 the Australian government put in place a new energy efficiency strategy for reducing energy consumption of electronic and electrical appliances while switched off or in standby mode to a maximum of 1 Watt. The policy objective was reducing both greenhouse gas emissions as well as consumer energy costs (estimated to be up to 10% of electricity bill). The actual case study started in 2007, with a lab wishing to gain NATA (National Association of Testing Authorities) accreditation for the measurement of standby power (a very low level of power). NATA, in turn, had to find expertise for performing such assessment. This was however made difficult because one of the Australian standards for measuring standby (and thus

<sup>15</sup> Ministry of Business, Innovation and Employment.

www.mbie.govt.nz/conformance.

<sup>&</sup>lt;sup>14</sup> Manufacturing, Standardization & Digital Solutions, European Committee for Standardization (CEN) - European Committee for Electrotechnical Standardization (CENELEC).

<sup>&</sup>lt;sup>16</sup> The New Zealand "Conformance System Strategy" and more information are available at:

<sup>&</sup>lt;sup>17</sup> CEO, National Association of Testing Authorities, Australia.

very low) power had a photograph of a measuring instrument that was not actually capable of performing such a task. Another challenge was that instrument calibration at low power levels was not available in Australia at that time. The core problem was measuring modern equipment, which often contain electronics that distort the supply current. This meant that instruments for measuring standby power must have the ability to measure highly distorted waveforms and at very low wattage. In response, Australia NQI had to develop new measurement capabilities in order to meet those energy efficiency policy objectives set by the Australian government in 2002. To this end: (i) NATA developed additional technical expertise to deal with unfamiliar aspects of the testing; (ii) standards underwent review and amendment; (iii) CABs (laboratories) acquired suitable instrumentation; and (iv) the National Measurement Institute developed calibration capability. For her, the following key lessons could be drawn from this case study: early and ongoing policy coordination with NQI bodies can avoid a mismatch between the regulatory objective and conformity assessment capabilities; and the importance of engaging in early cooperation and coordination between NQI bodies to resolve issues about national capabilities. Additionally, what was learned by the NQI from the standby power issues was also beneficial later for new similar situations (e.g. measurement issues around developments in LED lighting). In conclusion, she said that the lessons learned can be summed-up as follows: "your NQI is an invaluable resource: consult early, consult often, and consult collaboratively".

1.10. Mr. André Iwasa<sup>18</sup> (Brazil) made a presentation on the new conformity assessment (CA) framework for telecommunications products in Brazil (October 2019). He started by providing an overview of the previous framework, established under Resolution 242 of November 2000, adopted by ANATEL (Brazil's National Telecommunications Agency, created in 1997). This framework was mainly based on type approval/certification, with priority for accredited third-party laboratories (declaration of conformity was allowed only in exceptional cases). Telecom products were divided into three categories: first, equipment directly used by consumers; second, equipment emitting radiofrequency but not used directly by consumers; and third, all equipment not included in the first and second categories. However, as a result of important developments in the ICT environment (high demand for connected devices, fast growth in equipment approvals and new connectivity ways such as 5G and IoT), a new framework was needed. To this end, in 2017 ANATEL started public consultations and sought proposals from stakeholders, eventually resulting in the adoption in October 2019 of the new framework under Resolution 715/2019. The main changes and improvements made were: (i) elimination of the homologation fee (thus representing a reduction of barriers for certification); (ii) revision of CAPs (thus providing more flexibility by allowing the technical area to define which CA model would be more appropriate for each product type, a decision to be also based on a risk analysis); and (iii) a new model of market surveillance: while ANATEL would be responsible for issuing operational procedures detailing market surveillance requirements, all market surveillance costs would be the responsibility of the certificate owners.

## Panel 5: NQI systems

1.11. Ms Jo-Anne Beharry<sup>19</sup> (Trinidad and Tobago) presented the steps her country is taking, and the challenge it is facing to strengthen its NOI, in particular when carrying out the following three initiatives: (i) "National Quality Policy" (NQP); (ii) "Regional Initiatives"; and (iii) promoting "stakeholder engagement". Regarding the NQP, she referred to the four key components of Trinidad and Tobago's new NOP Implementation Plan: Component 1 - formation of governance bodies: Quality Councils, Project oversite offices; Component 2 - review of legislation to clearly define mandates, avoid overlaps and address regulatory gaps; Component 3 - address institutional strengthening: eempowerment of institutions and capacity building; and Component 4 - building a "quality conscious society". Regarding "Regional Initiatives", she mentioned the work of the CROSQ ("CARICOM Regional Organization for Standards and Quality") in coordinating approaches to QI development at the regional level, taking advantage of national competencies. Regarding "stakeholder engagement", she underscored the importance of promoting various forms of engagement, both prior to, as well as during, regulatory implementation. She also noted that the various thematic sessions during the national launching of the NQP, in early November, was actively attended by many high-level participants. She concluded by listing various key lessons learned from this process. First, in the absence of a policy, the infrastructure may be developed in an *ad hoc* manner and may not relate to national development priorities. Second, a robust gap analysis of the system would be needed: if legislative roles were to be clearly defined; or for avoiding overlap of

<sup>&</sup>lt;sup>18</sup> Process Coordinator, National Telecommunications Agency (ANATEL).

<sup>&</sup>lt;sup>19</sup> Standards Officer III, Trinidad and Tobago Bureau of Standards.

responsibilities; or for establishing a baseline for monitoring and evaluation. Third, regional initiatives are useful for supporting buy-in at the national level. Fourth, funding mechanisms should be identified for implementation. And lastly, governments should champion initiatives to foster buy-in and engage stakeholders by relating the NQP to their specific areas of interest.

1.12. Mr. WANG Yunsong<sup>20</sup> (China) started his presentation on China's QI, listing the two sets of elements supporting it: policies (the "Quality Development Outline (2011-2020)", the "Guidance on Launching Quality Improvement Actions", and the "Guidance on Strengthening the Construction of the Quality Certification System and Promoting Comprehensive Quality Management") and laws and regulations (the "Product Quality" and "Metrology" laws, and the "Regulations on Certification and Accreditation"). He then gave an overview of China's QI institutional and technical settings, which has the "State Administration for Market Regulation" (SAMR) on the top and, under it, the following four quality and technical institution at the national level: (i) "National Institute of Metrology" (NIM), "China National Institute of Standardization" (CNIS), "China National Accreditation Service for Conformity Assessment" (CNAS), and "China Quality Certification Center" (CQC). He then gave a detailed explanation of various aspects of China's QI, including with respect to: the development and adoption of national standards; the designation of certification bodies; and the work of inspection and testing institutions. He, in turn, presented the recent reform of China's QI and regulatory frameworks, the purpose of which was: to streamline the organization, simplify procedures, improve operational efficiency, reduce enterprise burdens, improve the business environment, support trade development, promote industrial upgrading, and protect the public interest. Key changes resulting from this reform included: improvements of the top-level design of quality policy, improvements in metrology and standardization practices and procedures, enhancements of cooperative services for quality infrastructure, and advancement of reform and innovation of market regulation. He then concluded offering the following three suggestions to the WTO: (i) adopting relevant guidelines to clarify the concepts, components, basic principles, policy framework, status and role of QI; (ii) more active participation in international exchanges and cooperation in the field of QI; and (iii) conduct in-depth discussions on various TBT-related law enforcement measures to promote information exchanges and cooperation in the field of market surveillance.

1.13. Ms. Sanem Yıldız<sup>21</sup> (Turkey) presented the Legal, Implementation and Inspection dimensions of Turkey's NQI. She explained that the main structure was established upon the Legal dimension and that there were two basic tenets underlying the legal infrastructure: the WTO and the Customs Union (CU) between EU and Turkey. As a member of the WTO since 1995, Turkey has had full faith in the benefits of free trade, abiding by WTO rules and its reflection in the TBT and SPS Agreements regarding technical legislation. She said that the other significant reference point of Turkey's technical legislation is the CU, which covers trade in manufactured products. Decision No 1/95 of the EC-Turkey Association Council, on implementing the CU's final phase, provided for Turkey's obligation to incorporate the Union's instruments related to the removal of technical barriers to trade into its internal legal order. Other important legal instruments were: (i) the Association Council Decision 2/97 (laying down the list of the Union's legal instruments, including part of the "acquis" on industrial products related to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey, as updated by the 2014 "procedural guidelines") and; (ii) the Association Council Decision 1/2006 (providing for the assignment of Turkish conformity assessment bodies and recognition of the test reports and certificates issued by those in Turkey). With respect to the Implementation dimension, she stated that standardization was a key element to pushing up exporting capacities and ensuring effectiveness as a way of reducing costs by minimizing waste and errors. Turkish Standards Institute became a full member of CEN/CENELEC in 2012 and 98% of its standards were harmonized with EU standards. She also described various improvements regarding Turkey's rules on CABs (in Turkey, there were about 1782 accredited CABs) as well as on Metrology and Accreditation. The Turkish Accreditation Agency, she said, was a full member of ILAC and IAF as well as European co-operation for Accreditation. She also highlighted the many changes and improvements between Turkey's 1995 NQI framework and the current one (2019), in terms of how they regulated accreditation, standardization, CAPs and metrology. With respect to Inspection, the third and last dimension, she referred to: (i) the import and export controls of various product groups carried out by Turkey's Trade Ministry through the "Risk-Based Trade Control System (TAREKS)"; various aspects of Turkey's system for market surveillance (carried out by nine different public authorities, under the coordination of the Ministry

<sup>&</sup>lt;sup>20</sup> Deputy Director General of Quality Development Bureau, State Administration for Market Regulation.

<sup>&</sup>lt;sup>21</sup> Senior Trade Expert, Ministry of Trade.

of Trade); and (iii) awareness-raising work undertaken in the areas of product safety, market surveillance and conformity assessment project. She also gave an overview of Turkey's "Technical Cooperation Agreements", which aimed to remove technical barriers to trade and promote unhindered market access for its exporters. Finally, in conclusion, she expressed the view that having a functional quality infrastructure at international level was crucial for the elimination of technical barriers to trade. Turkey, she said, was ready to extend its efforts to realize cooperative activities with the aim of exchanging information and experience on technical legislation, facilitate the solution of technical barriers to trade, and provide a basis to develop technical cooperation between the parties' bodies responsible for standardization, accreditation and metrology.

1.14. **Mr. Matías Bernocco<sup>22</sup>** (Argentina) provided an overview of Argentina's new National Quality System.<sup>23</sup>

1.15. **Mr. Warren Merkel<sup>24</sup>** (United States) presented an overview of the NQI in the United States, which follows a market-based approach. The US encourages communication and competence in the use of NQI by US regulators, in order to avoid unnecessary barriers to trade.

1.16. Metrology was recognized as vital for economic success in the United States 231 years ago, when fixing the standards of weights and measures was included in the US constitution. NIST is the US national metrology institute, and it communicates and collaborates actively with regional metrology organizations and the BIPM. While policy makers often overlook the need for sound metrological infrastructure, gaps therein undermine further activities of the QI and require significant resources and time to address.

1.17. Standardization in the US is market-driven and private sector led, supported by a longstanding public-private partnership between NIST and ANSI. The National Technology Transfer and Advancement Act of 1995 (NTTAA) and the Office of Management and Budget Circular A119 set out obligations for government use of voluntary consensus standards, and assign NIST to coordinate with the private sector, and cooperate with other stakeholders (public, private, other governments, international organizations and private organizations) in setting standards. As part of the Interagency Committee on Standards Policy, Standards Executives in federal agencies are a key channel of communication on the latest developments in standardization and provide access to the appropriate competence when regulators within an agency are considering standards-related issues.

1.18. The US has a wide range of private sector conformity assessment bodies, and government policy is to use private sector conformity assessment where possible and consistent with policy objectives. The NTTAA also calls on NIST to coordinate conformity assessment activities, to eliminate unnecessary duplication and complexity. However, the inherent complexity of conformity assessment poses challenges for regulatory agencies developing conformity assessment programmes, as they must quickly access the required competence in the public or private sector. NIST provides support, practical information and guidance through the "NIST Special Publication 2000-2, Conformity Assessment Considerations for Federal Agencies".

1.19. Accreditation in the US also follows a market-based approach – there are seven US accreditation bodies that are signatories to the ILAC and/or IAF arrangements (six of which are private). Many of these accreditation bodies are sector-specific and predate the ILAC/IAF arrangements. They provide effective, timely and relevant access to accreditation, which underpins commerce in the US.

1.20. One key challenge is communication and awareness on QI throughout government, and with the actual regulatory decision makers. A second challenge is ensuring that appropriate competence on QI is available and engaged by regulators in the development of technical regulations.

1.21. **Mr. Alfredo Sitoe<sup>25</sup>** (Mozambique) provided an overview on Mozambique's technical assistance needs in the area of quality infrastructure. Mr Sitoe gave an overview of Mozambique and the work of his country's national standards body, *Instituto Nacional de Normalização e Qualidade* –

<sup>&</sup>lt;sup>22</sup> Director of Technical Regulations and Quality Promotion.

<sup>&</sup>lt;sup>23</sup> <u>G/TBT/GEN/270</u>.

<sup>&</sup>lt;sup>24</sup> Chief of Standards Services, Standards Coordination Office, National Institute of Standards and Technology (NIST).

<sup>&</sup>lt;sup>25</sup> Director, *Instituto Nacional de Normalização e Qualidade* (INNOQ).

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INNOQ, a public institution created in 1993 under the supervision of the Minister of Industry and Trade with responsibilities in the area of standardization, metrology, certification, testing and inspection. Mr. Sitoe provided an overview of Mozambique's National Quality System Act (2018) and emphasized his country's need for technical assistance to effectively implement the Act, and to support demands from clients for accredited services in Metrology, Certification, Testing and Inspection. In particular, there was a need, in the area of certification for: (i) training of 60 auditors; and (ii) consultancy to design certification schemes for products such as Soja, Tea, Bananas, Sesame, Peanuts, Tobacco, Peas, Macadamia, Maize, Cassava, Beans, Cotton and related products, including "Global Good agricultural practices" (Global GAP) and organic certification. With respect to testing and inspection there was need for: (i) training of 20 technicians for testing and inspection; and (ii) equipment for testing (Chemical and Microbiology) and inspection Labs. For metrology, there was a need for: (i) the training of 38 technicians in diverse fields; (ii) reference standards for verification of gas flow totalizers, ovens, digital readers, thermocouples, calibrators of gas flow, temperature meters, digital thermometers, climatic chamber, mass standards, standards for length, pressure, electrical, large volumes, strength. In addition, there was a need for technical assistance on accreditation with respect to management systems and products, testing and inspection, and calibration of measuring instruments in various fields.

1.22. Léa Contier<sup>26</sup> (Brazil) described the background and organization of Brazil's National Quality Infrastructure. The Brazilian Association of Technical Standards (ABNT) is the sole standardisation body in Brazil, while the National Institute of Metrology, Quality and Technology (INMETRO) is responsible for legal and scientific metrology, including through the Brazilian Network for Legal Metrology and Quality. The INMETRO Coordenação Geral de Acreditação (CGCRE) is responsible for accreditation. Brazil's current product safety regulatory system is quite heavy and prescriptive, covers only 12% of products, and is not aligned with international best practices, leading to low performance. The new regulatory model for products under the scope of INMETRO aims at increasing product coverage and performance, with reduced bureaucracy, greater resource efficiency, simplification and flexibility. It will include a General Regulation, and transverse regulations for specific risks or product groups, with a focus on problem solving through a monitoring strategy. A public call for comments was notified in July 2019<sup>27</sup>, and the development of the General Regulation is expected in 2020.

## Panel 6: Regional approaches to QI

1.23. Mr. Sbu Khumalo<sup>28</sup> (South Africa) described how quality infrastructure supports cooperation in the SADC (South African Development Community) region on the development and implementation of technical regulations. The mandate is derived from the TBT Annex to the SADC Protocol on Trade and the relevant regional structures include, SADC Technical Regulations Liaison Committee (SADCTRLC). The SADCTRLC approach to cooperation on technical regulations is approximation of technical relations to determine equivalence and hence accepting of each other's conformity assessment results. This involves technical comparison of SADC members' national legislation in a specific sector to determine convergences and divergences. Aspects for comparison during approximation include: features of the legislation (name, type, enforcer, and responsible institutions), administrative provisions, legal or provisional requirements, conformity assessments procedures, and technical requirements. The process entails acknowledging each other's technical regulations and where divergences are causing trade problems, the SADCTRLC provides the platform for discussion and cooperation thereof at SADC member states level. The approximated technical regulations are on cement and fish and fishery products, conformity assessment procedures, amongst others, while proposed projects covered sectors such as transportation, energy efficiency of electrotechnical products and labelling of wine. Some lessons learned were on the importance of information sharing and transparency, understanding similarities in the use of standards, and managing differences in conformity assessment procedures. However, there are differences on conformity assessment procedures in the SADC region which subject countries to double testing and non-acceptance of accredited test reports. The proposal is that further discussions and possible quidelines on conformity assessment procedures at the WTO level is sought.

<sup>&</sup>lt;sup>26</sup> National Institute of Metrology Standardization and Industrial Quality (Inmetro).

<sup>&</sup>lt;sup>27</sup> <u>G/TBT/N/BRA/890</u>.

<sup>&</sup>lt;sup>28</sup> Deputy Director, Technical Infrastructure of the Industrial Development Division of the Department of Trade and Industry of South Africa.

1.24. Ms Mere Falemaka<sup>29</sup> (Vanuatu/Pacific Islands Forum Secretariat) gave an overview of the three components of the 2003-2007 Pacific Regional Trade Facilitation Program (RTFP), namely customs strengthening, biosecurity, and standards and conformance (S&C). Studies as part of the RTFP highlighted the low to non-existent level of development of S&C among Pacific Island Countries (PICs) (notably only Fiji and Papua New Guinea have QI institutions and systems in place) and called for a regional approach. Despite the recommendations of the RTFP, work on S&C did not progress for a variety of reasons, including the lack of awareness as to the benefits of a QI system, high costs of QI investment, limited expertise, lack of regional institutions, and the nature of PICs trade being predominantly raw and semi-processed products. As of 2019, the trading environment of PICs had evolved towards more diverse exports (value-added, processed goods) whilst consumers became more demanding on quality and standards. Nevertheless, QI development in PICs has remained low, despite instances of non-compliance with standards hindering trade, which represents a missed opportunity to facilitate exports. In order to improve this situation and enhance international competitiveness, the promotion of a culture of quality through QI systems was deemed a priority, based on the nature of trade of each PIC, and via the incremental establishment of pathways for those lacking physical infrastructure. In order to determine the way forward, a Pacific Regional QI Workshop was held in September 2019. The objectives of workshop included a stock-take of QI systems in PICs, experience sharing and the promotion of institutional partnerships on QI. The workshop bore several outcomes: (i) a Regional Quality Statement, committing PICs to develop QI systems; (ii) establishment of a network of national QI focal points; and (iii) development of a Regional Quality Policy and Concept Note to outline the Pacific QI Strategy, to be endorsed by Forum Trade Ministers in February 2020.

1.25. Ms Ileana Martinez<sup>30</sup> (United States) provided some background to the creation of the Quality Infrastructure Council of the Americas (QICA), explaining that in 2011 the countries of the region of the Americas understood the need to have access to internationally recognized QI services to foster competitiveness, innovation, trade, and consumer safety. The key elements of a quality infrastructure were identified as standards development, accreditation and metrology, because of their complementary and mutually supportive nature. This process led to the creation of QICA in 2014, signed by leaders of the three regional IQ organizations (COPANT<sup>31</sup> – standardization, IAAC<sup>32</sup> - accreditation, and SIM<sup>33</sup> - scientific and legal metrology). The main goals of QICA are the strengthening of each country's NQI, promotion of the importance of QI services, collaboration and information sharing among peers at the national level, organization of regional and national activities, and cross-functional training. Indeed, QICA has participated in awareness-raising activities, promotion of co-operation among national members, and provision of training across standardization, accreditation and metrology. More specifically, to better reach regulators, QICA initiated a programme of outreach in 2017 in smaller, more informal settings, allowing open dialogue among regulators/stakeholders and their national QI institutions. QICA will continue to raise awareness of NQI, and design more effective mechanisms to determine the needs of stakeholders and demonstrate how QI services can meet those goals.

### COMMENT BY MODERATORS

1.26. On a personal note, **the Moderators** made the following remarks.

1.27. This thematic session explored the four main pillars of the quality infrastructure: accreditation, metrology, standards and conformity assessment procedures – and how they support one another. We discussed how these pillars function cohesively within an NQI system, its importance for trade facilitation, as well as regional efforts to cooperate on this area.

1.28. I would say that National Quality Infrastructure resembles a delicate ecosystem, where different actors and elements have a unique role and at the same time coexist and mutually complement each other.

<sup>&</sup>lt;sup>29</sup> Permanent Representative and Ambassador, Permanent Delegation of the Pacific Islands Forum to the United Nations, WTO and Other International Organisations in Geneva.

<sup>&</sup>lt;sup>30</sup> Principal, Standards, Accreditation and Trade Advisors, representing QICA.

<sup>&</sup>lt;sup>31</sup> The Pan American Standards Commission.

<sup>&</sup>lt;sup>32</sup> The Inter American Accreditation Cooperation.

<sup>&</sup>lt;sup>33</sup> The Inter-American Metrology System.

1.29. **Accreditation** is the highest level of confidence in the NQI chain. Members shared the efforts of the accreditation bodies to cooperate regionally and globally through ILAC/IAF MRA/MLA. Presentations underlined the importance of further promoting the mutual acceptance of accreditation and conformity assessment results from accredited conformity assessment bodies at international, regional and bilateral level.

1.30. On the other hand, **Metrology** is essential for supporting innovation, conformity assessment activities and consumer protection, as well as the work of regulators. Sound measurements are achieved by ensuring metrological traceability to internationally agreed standards with the appropriate measurement uncertainty.

1.31. A range of **standardization** approaches are used to support the NQI, and speakers highlighted the importance of coherence with international standards, public-private partnerships, and broad stakeholder representation in standards development, including participation of SMEs.

1.32. Members shared case studies of **conformity assessment** in specific sectors and highlighted the importance of applying good regulatory practices, such as public consultation and reviewing performance over time. Coordination between and amongst NQI bodies and regulators was important to ensure that regulatory objectives can be effectively met through national technical capacities.

1.33. Through the sessions, we heard about several different **NQI systems**, and reforms and progress of these systems. Several points were mentioned, including: the importance of national legal and policy frameworks for governance of the QI; the need for stakeholder engagement and communication; and the role of market surveillance in the QI. We also discussed the need for sustained demand-driven technical assistance to support NQI improvement in developing and least-developed countries.

1.34. **Regional cooperation on QI** can help by pooling resources, promoting alignment of national regulatory approaches using QI, and information sharing and collaboration to facilitate trade. Challenges can arise with respect to differences amongst regional partners in terms of diverse levels of NQI development, and lack of awareness of QI including amongst regulators.

1.35. In our view, this was a very rich session, with many important insights worthy of further reflection. There was some discussion about next steps in the Committee to follow up. There was a suggestion that the Committee consider the principles and policy frameworks of QI. Another idea was for the Committee to study specific trade concerns related to conformity assessment procedures, to better understand the types of procedures that most frequently give rise to concern. We notice that Members have showed strong common interests on NQI and believe there is scope for further work in this area. In this regard, we look forward to fruitful discussions in the Committee.

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### ANNEX

## THEMATIC SESSION ON CONFORMITY ASSESSMENT PROCEDURES: NATIONAL QUALITY INFRASTRUCTURE

12 NOVEMBER 2019, 15:00-18:00 - 13 NOVEMBER 2019, 10:00-13:00

### Programme<sup>1</sup>

At the Eighth Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with its regular meetings during 2019 to 2021, with a view to further deepening the Committee's exchange of experiences on specific topics, and to hold a session on conformity assessment procedures (CAP) in November 2019 with a focus on: National Quality Infrastructure (NQI).<sup>2</sup>

This thematic session will be moderated by: Mr. BI Zhonglin (China) and Ms Lorena Rivera (Colombia)

Guiding questions:<sup>3</sup>

- What approaches exist for the development of NQI, including metrology, standardization, conformity assessment and accreditation?
- How can Members encourage the use of NQI by their regulators, in order to avoid unnecessary barriers to trade?

Speakers are invited to make presentations not exceeding 15 minutes.

### Panel 1: Accreditation

- a. **Indonesia**: *Indonesia's experience on the use of Accreditation as a basis for conformity assessment acceptance*, Mrs. Konny Sagala, Director of Implementation System for Standard and Conformity Assessment, BSN.
- b. **European Union**: Overview of the system for accreditation in the EU as part of National Quality Infrastructure, Mr. Andreas Steinhorst, Executive Secretary, European cooperation for Accreditation.
- c. **Egypt**: *Outline and brief on quality infrastructure development in Egypt*, Eng. Hany El-Desouki, Executive Director, and Eng. Mohamed Abdelhalim, Head of International Relations Department, Egyptian Accreditation Council.

### Panel 2: Metrology

a. **International Bureau of Weights and Measures (BIPM)**: A common international approach to Quality Infrastructure – recent developments", Mr. Andy Henson, Director of International Liaison and Communication Department, BIPM.

### Panel 3: Standardization

a. **Japan**: *Standardization Process in Japan's Quality Infrastructure*, Ms Yukiko Kotani, Japanese Standards Association Group.

<sup>&</sup>lt;sup>1</sup> The draft programme is contained in <u>JOB/TBT/342/Rev.1</u>.

<sup>&</sup>lt;sup>2</sup> <u>G/TBT/41</u>, para. 8.2.a.iv, footnote 298; <u>JOB/TBT/273/Rev.5</u>, para. 2.2.a.

<sup>&</sup>lt;sup>3</sup> <u>G/TBT/41</u>, para. 4.17.c.iv.

- b. **United States**: *Standardization in the United States National Quality Infrastructure*, Ms Leslie McDermott, Director, International Development, American National Standards Institute (ANSI).
- c. **European Union**: *The role of standards in Quality Infrastructure*, Mr. Gonçalo Ascensão, Manufacturing, Standardization & Digital Solutions, European Committee for Standardization (CEN) - European Committee for Electrotechnical Standardization (CENELEC).

## **Panel 4: Conformity Assessment Procedures**

- a. **New Zealand**: *The Approach to conformity assessment the New Zealand experience*, Mr. Adam Dubas, Ministry of Business, Innovation and Employment.
- b. **Australia**: *Matching conformity assessment procedures with NQI capacity a case study in energy efficiency regulation*, Ms Jennifer Evans, CEO, National Association of Testing Authorities, Australia.
- c. **Brazil**: *New conformity assessment framework for telecommunications products in Brazil*, Mr. André Mota de Abreu Iwasa, Process Coordinator, National Telecommunications Agency (ANATEL).

## Panel 5: NQI systems

- a. **Trinidad and Tobago**: *Steps in the Strengthening of the Quality Infrastructure A Developing Country Perspective*, Ms Jo-Anne Beharry, Standards Officer III, Trinidad and Tobago Bureau of Standards.
- b. **China**: *China's quality infrastructure*, Mr. WANG Yunsong, Deputy Director General of Quality Development Bureau, State Administration for Market Regulation.
- c. **Turkey**: *Quality Infrastructure in Turkey*, Ms. Sanem Yıldız, Senior Trade Expert, Ministry of Trade.
- d. **Argentina**: Regulatory Strategy of the Argentine Republic. The new National Quality System – the role of the Technical Regulators Commission and the harmonization of conformity assessment procedures. Presentation on Argentina's experience in the use of international standards as a tool to access international markets, Mr. Matías Bernocco, Director of Technical Regulations and Quality Promotion.<sup>4</sup>
- e. **United States**: *National Quality Infrastructure of the United States*, Mr. Warren Merkel, Chief of Standards Services, Standards Coordination Office, National Institute of Standards and Technology (NIST).
- f. **Mozambique**: *INNOQ's technical assistance needs*, Mr. Alfredo Sitoe, Director, *Instituto Nacional de Normalização e Qualidade* (INNOQ).
- g. **Brazil**: *The Brazilian National Quality Infrastructure: an overview and recent developments*, Léa Contier, National Institute of Metrology Standardization and Industrial Quality (Inmetro).

## Panel 6: Regional approaches to QI

a. **South Africa**: Southern African Development Community (SADC) Quality Infrastructure in relation to cooperation to demonstrate equivalence of technical regulations in the SADC Region, Mr. Innocent Sbu Khumalo, Deputy Director, Technical Infrastructure of the Industrial Development Division of the Department of Trade and Industry of South Africa.

<sup>&</sup>lt;sup>4</sup> <u>G/TBT/GEN/270</u>.

- b. **Vanuatu**: Regional Quality Infrastructure: The Pacific experience, Ms Mere Falemaka, Permanent Representative and Ambassador, Permanent Delegation of the Pacific Islands Forum to the United Nations, WTO and Other International Organisations in Geneva.
- c. **United States**: Regional Perspective on NQI, Ms Ileana Martinez, Principal, Standards, Accreditation and Trade Advisors, representing Quality Infrastructure Council of the Americas (QICA).