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Page: 1/4

Committee on Technical Barriers to Trade

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THEMATIC SESSIONS ON CONFORMITY ASSESSMENT PROCEDURES¹

REPORT BY THE CHAIRPERSON TO THE TBT COMMITTEE²

This Report was delivered by the Chairperson of the WTO TBT Committee at the meeting of 9-10 March 2016.

At the Seventh Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with regular meetings of the Committee,³ and agreed to dedicate the 8 March 2016 thematic sessions to the topics of conformity assessment procedures and good regulatory practice. The thematic session on conformity assessment procedures focused on developments in international and regional systems, and regional trade agreements (RTAs), relating to the recognition and acceptance of conformity assessment results.⁴ The presentations summarized below will be made available through the WTO website.⁵

1. **Dr. Chun Lee** (Chinese Taipei) presented results of a survey of Chinese Taipei firms showing that the main benefits of performing conformity assessment locally was time savings, followed by better communication with labs, and cost reduction. Referring to the indicative list of approaches adopted by the TBT Committee⁶, Chinese Taipei most often uses mutual recognition arrangements (MRAs), although there were limits to effectiveness such as their cost and time consuming nature, rigidity and limitation in scope (coverage list can rapidly become obsolete), and difficulty in prioritizing MRA partners. Supplier's declaration of conformity (SDoC) are used in FTAs on a product or sector specific basis, albeit with a smaller scope than applied in domestic regimes, but required robust market surveillance capacity which poses challenges for Members that follow a pre-market certification system. A new approach in FTAs was to permit participation of CABs (in terms of accreditation, approval, licensing) on a national treatment basis, exemplified in Article 6.1 of the Agreement between New Zealand and the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu on Economic Cooperation (ANZTEC). This approach required supporting measures, for example, that CABs need not be located in, or have an office or physical presence, in a Member in order to perform conformity assessment activities in that Member. The Canada-EU CETA provides an example of deeper integration, ensuring the application of national treatment for CABs on the basis of recognition, accreditation and designation of non-governmental CABs for performing conformity assessment activities on a specific list of products (subject to future review). Overall, national treatment for CABs was more time and cost effective, and mitigated issues of rigidity and obsolescence, particularly when there was the possibility for expansion of scope.⁷

2. **Mr. Kukuh Achmad** (Indonesia) introduced Indonesia's new law on standardization and conformity assessment (Law No. 20/2014) as well as the interplay between the various related business processes. Compliance to *Standar Nasional Indonesia* (SNI) is voluntary, except when relating to health and safety in which case SNI may be stipulated as mandatory by respective

¹ The list of speakers is contained in JOB/TBT/169.

² Alana Maria Lanza Suazo (Honduras). This Report is provided on the Chairperson's own responsibility.

³ G/TBT/37, para. 8.3.

⁴ G/TBT/37, para. 3.9(e).

⁵ https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

⁶ G/TBT/1/Rev.12, pp.45-46.

⁷ The full presentation is contained in document RD/TBT/123.

government ministries. In case of mandatory SNI, conformity assessment activity must be performed by KAN-accredited CABs that have been designated by respective regulators. Designation was followed because regulators have full responsibility for ensuring conformity with their requirements. The recognition of competency of foreign CABs occurs through bilateral or multilateral recognition agreements following a reciprocal principle. With respect to international recognition, KAN is a signatory of the ILAC MRA and APLAC MRA, as well as the IAF MLA and PAC MLA. To date KAN has accredited over 1,200 laboratories and inspection bodies, and over 200 CBs.⁸

3. **Dr. Elsabe Steyn** (South African) explained that a review of the TBT Annex of the Southern African Development Community (SADC) Trade Protocol had been undertaken in 2014 partly to enhance discussion of SADC TBT issues at the regional level. There are a series of SADC TBT committees and cooperation structures in the areas of: technical regulations (to promote the use of good regulatory practices); stakeholder participation (to enhance private sector participation in SADC quality infrastructure matters); accreditation; legal metrology; measurement traceability; standardization; and TBT expert advisory. In the area of accreditation, the SADC Cooperation in Accreditation (SADCA) helps to facilitate national, regional and international recognition and acceptance of conformity assessment results through the 3 accreditation bodies in the region namely the South African National Accreditation System (SANAS), the Mauritius Accreditation System (MAURITAS) and the SADC Accreditation Service (SADCAS), which is the world's first multi-economy accreditation body serving the other SADC countries. In the context of the Pan-African Quality Infrastructure (PAQI) initiative, the African Accreditation Cooperation (AFRAC) aims to cooperate and expand accreditation awareness and capacity throughout Africa with a view to expand the AFRAC Mutual Recognition Agreement between the African accreditation bodies to facilitate the acceptance of conformity assessment results.⁹

4. **Mr. Tomoyuki Kinoshita** (Japan) introduced two examples of sectoral international schemes that could facilitate the acceptance of test results in other countries, recalling a recommendation of the Seventh Triennial Review. First, Japan described the IECEE CB Scheme, an international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products. Reliability of test results is ensured because under the scheme National Certification Bodies (NCBs) and CB Testing Laboratories (CBTLs) must meet relevant international standards, testing is based on relevant IEC standards, and there is ongoing peer assessment amongst Member NCBs and CBTLs to ensure technical competence to carry out tests against IEC standards. Second, Japan introduced the OECD principles of Good Laboratory Practice (GLP) to be followed by test facilities carrying out studies assessing the health and environmental safety of chemicals, and Mutual Acceptance of Data (MAD), to promote acceptance of non-clinical chemical safety studies amongst participating Members. To ensure reliability, national GLP compliance monitoring programs and periodic peer assessments are applied. Both the IECEE CB and OECD schemes help to reduce duplicative testing and save government and industry resources, and Japan explained how they are applied in the context of Japan's national regulations.¹⁰

5. **Mr. Guillaume Parent** (Canada) described his country's approach to conformity assessment and summarized the different categories based on examples as applied in Canada (e.g. SDoC for low risk products like motor vehicles, recreational craft, and electromagnetic compatibility; third party for medium risk products like telecom, electrical products, construction products and organics; Government Assessment for products of high risk like pharmaceuticals and medical devices). Canada approaches acceptance of conformity assessment results in FTAs on a case-by-case basis, while striving towards the ideal of "one standard, one test, one certificate, accepted anywhere". In this respect, Canada prefers national treatment of conformity assessment bodies (CABs), providing for recognition (including designation, registration, approval, licensing and notification) of foreign CABs on conditions no less favourable than applied to domestic ones, citing the example of Article 8.6 of the TPP. In terms of other approaches, Canada encourages the use of voluntary Multilateral Accreditation Arrangements (MLAs). Finally, MRAs are also used but are the

⁸ The full presentation is contained in document RD/TBT/124.

⁹ The full presentation is contained in document RD/TBT/125.

¹⁰ The full presentation is contained in document RD/TBT/126.

least favoured approach, as these are difficult to negotiate, implement, and benefits difficult to measure – even though they can be useful for certain sectors such as telecoms.¹¹

6. **Ms. Esther Peh** (Singapore, on behalf of ASEAN) highlighted ASEAN's achievements on standards and conformance. ASEAN's work in the acceptance and recognition of conformity assessment results has facilitated the flow of goods within the region, led to reduced cost for traders and faster time-to-market for goods. The ASEAN Consultative Committee for Standards and Quality (ACCSQ) undertakes work on standards harmonization, MRAs and harmonized regulatory regimes. The ASEAN Framework Agreement on MRAs provides a template for the development of sectoral MRAs in ASEAN. ASEAN introduced examples of MRAs and harmonized regulatory regimes in three sectors: Electrical and Electronic Equipment (EEE) (based on IECCE CB scheme), pharmaceuticals (based on Pharmaceutical Inspection Co-operation Scheme – PIC/S), and cosmetics. Despite differences in ASEAN Member States' national standards and conformance systems and levels of development, these sectoral initiatives delivered important benefits due to the willingness and commitment of all ASEAN regulatory authorities to collaborate.¹²

7. **Ms. Ann Weeks** (United States) offered the perspective of a conformity assessment body on the benefit of conformity assessment provisions in FTAs, focusing on questions of: market access (can services be provided?); parameters for providing services (e.g. is a local presence required to provide services?); and fair competition (are all conformity assessment bodies treated equally?). She said that public-private partnerships were important for facilitating trade in conformity assessment without sacrificing the quality of the conformity assessment programme. The TBT Chapter of NAFTA (Article 908.2) was as presented an example that enables recognition of conformity assessment bodies of NAFTA parties through accreditation. Further, the example of TPP was mentioned, both in terms of facilitating business case decisions on the location of laboratories so as to provide the most cost effective services (Article 8.6.4), and how regulatory coherence could enable private sector conformity schemes to fulfil regulatory requirements (Articles 25.5.2 and 25.5.8). Finally, that fact that the WTO TBT Agreement maintained neutrality with respect to approaches to conformity assessment was crucial, given the dynamic nature of risk, including in areas like the "internet of things" and "3D printing".¹³

8. **Mr. Sebastien Morard** (Switzerland) explained how the Switzerland-China FTA had used OIML standards to recognise test results and to reduce the costs of CAP in weighing instruments. The FTA refers to relevant international standards. It includes a side Agreement on mutual recognition of test results of measuring instruments. This side Agreement provides for recognition of tests carried out in the other Party in line with OIML recommendations, on the basis of the issuance of OIML test reports, which are then recognized by the other Party for the purposes of type approval in their market, according to their technical regulations. So far, 18 product types had been recognized in two years of the operation of the Agreement; it was no longer necessary to ship specimens for testing in the export market. Building on the foundation of the OIML Mutual Acceptance Arrangement and standards, this mutually-beneficial case study shows that test results can be recognised based on reliable international standards and schemes, despite differences in legislation.¹⁴

9. **Mr. Javier Arregui** and **Ms. Nike Bönnen** (European Union) outlined proportionality and recognition (or lack thereof) as two inter-related trade aspects of conformity assessment. The EU approach to conformity assessment in FTAs included: a joint commitment to choose the least burdensome procedure on basis of risk assessment and GRP principles to ensure fitness for purpose; reference to existing multilateral schemes (e.g. ILAC, IAF) where positive assurance of conformity is required; sector-specific provisions such as use of UNECE type approval certificates for motor vehicles or SDoC for electronics; and, integration of existing bilateral MRAs into FTAs. While traditional MRAs do provide a one-stop shop for manufacturers, there are a number of drawbacks such as high administrative burdens (e.g. CAB designation procedure, need for regular updates of lists of applicable laws and regulations), and the fact that they freeze the status quo and give little incentive for further regulatory convergence. On the other hand, enhanced MRAs based on regulatory alignment, which extend the EU internal market in specific product sectors to

¹¹ The full presentation is contained in document RD/TBT/127.

¹² The full presentation is contained in document RD/TBT/128.

¹³ The full presentation is contained in document RD/TBT/129.

¹⁴ The full presentation is contained in document RD/TBT/130.

interested EU neighbours, offer greater benefits, but require a higher degree of cooperation as well as convergence in the areas of standards and quality infrastructure.¹⁵

10. **Mr. Xinhua Sun** (China) set the scene by recalling the obligations for recognition of conformity assessment procedures contained in the TBT Agreement, and the indicative list of approaches adopted by the TBT Committee.¹⁶ Focusing on MRAs, China's approach was reflected in its "Regulations of the People's Republic of China on Certification and Accreditation", which encourages MRAs based on equality and mutual benefit. China exemplified its approach by introducing the China-New Zealand FTA, which was China's first FTA negotiated with a developed Member. The annex of this FTA focuses on collaboration in context of the EEE MRA and seeks to reduce compliance costs and facilitate trade while assisting regulators in managing risks related to electrical safety and EMC, as well as reducing language barriers. The EEE MRA covers products listed in the CCC catalogue and also requires SDoC to access the market of New Zealand. New Zealand manufacturers can have their products tested and certified in a New Zealand testing laboratory and certification body accepted by CNCA and thereafter a CCC certificate and a CCC mark can be issued to allow placing on the Chinese market. Conversely, Chinese manufacturers can have their products tested and certified in a testing and certification body designated by CNCA of China, demonstrating compliance with CCC certification requirements and the deviations for the product standards required by New Zealand. Once a CCC certificate is issued, this can be used as a basis of SDoC for placing on the New Zealand market. An expansion of the scope of the EEE MRA is currently under discussion. As a second example, China mentioned the China-Korea FTA, signed in 2015. Under this FTA framework, CNCA of China and KATS of Korea signed an EEE MRA. The objective of the FTA was to achieve mutual recognition of EEE conformity assessment results and certificates.¹⁷

11. **Mr. Abel Hernández Pineda** (Mexico) introduced the development of Mexico's system for conformity assessment and mutual recognition agreements. He said that regulators were currently more actively seeking to work in line with WTO agreements and that Mexico had recently published 25 new technical regulations and pursued 10 constitutional changes concerning conformity assessment. He said that conformity assessment is mostly carried out by private institutions in Mexico. An example on washing machines was provided: washing machines require three technical regulations to attain relevant certification – for safety, energy efficiency, and labelling for commercial information. He introduced a pilot project on safety requirements of electric products – where the new regulation is based on ISO/IEC 17067:2013. He said that while some national variations are sometimes needed, international schemes such as those of the ISO/IEC system were used for certification. To enable and improve MRAs, Mexico had initiated a program for international cooperation. In this regard, the Mexican Council for Standardization and Conformity Assessment (COMENOR) cooperates with several international laboratories for the purpose of offering fast and reliable solutions for foreign manufacturers so as to enable them to obtain the Mexican NOM mark.¹⁸

¹⁵ The full presentation is contained in document RD/TBT/138.

¹⁶ G/TBT/1/Rev.12, pp.45-46.

¹⁷ The full presentation is contained in document RD/TBT/132.

¹⁸ The full presentation is contained in document RD/TBT/137.