WORLD TRADE ORGANIZATION

G/TBT/GEN/323

28 March 2022

(22-2560) Page: 1/6

Committee on Technical Barriers to Trade

THEMATIC SESSION ON CONFORMITY ASSESSMENT PROCEDURES (ACCREDITATION)

8 MARCH 2022, 10:00-13:00

Moderator's Report[1]

At the Ninth Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with its regular meetings during 2022 to 2024, with a view to further deepening the Committee's exchange of experiences on specific topics. On this basis, the Committee agreed to hold a thematic session on conformity assessment procedures with a focus on accreditation.[2] Information about the speakers, presentations, and related materials are available on the WTO website.[3]

1 GUIDING QUESTIONS

- How can accreditation and related policies of Members be advanced to further reduce barriers to trade in goods? How can the ILAC and IAF, and cooperation between accreditation systems, be leveraged to avoid such barriers?
- How has accreditation landscape changed in the past 25 years since the TBT Agreement was drafted, and is there a need for further Committee guidance on accreditation considering this?
- How can accreditation (and accreditation policies) help permit participation of CABs located in the territories of other Members in their CAPs on a national treatment basis, in light of multiple approaches to support a trusted accreditation regime?

2 INTERVENTIONS

2.1. **Mr. Fei Yang**[4] (China) explained how accreditation facilitates export of masks and other epidemic prevention products. After the outbreak of COVID-19, there was fast-growing demand for China-manufactured anti-epidemic products including facemasks, protective gloves, protective suits and other personal protective equipment. However, standards and conformity assessment procedures for those products, he noted, are not harmonized across countries and referred, as an example, to differences between the standards of China and the European Union for facemasks. In particular, he noted that EU regulations require facemasks for medical use and personal protection to be certified by notified bodies and that Chinese manufacturers encountered difficulties in satisfying these requirements.

2.2. Mr Fei Yang further explained that the European Commission issued Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of COVID-19, allowing EU member States to grant access to Chinese facemasks manufactured and tested according to Chinese standards as long as testing laboratories are accredited by the China National Accreditation Service for Conformity Assessment (CNAS). In response to these developments, CNAS cooperated with European Accreditation (EA) and

---

[1] Mr. Hélio Silva (Brazil). This Report is provided on the Moderator's own responsibility.
[2] G/TBT/46.
[3] https://www.wto.org/english/tratop_e/tbt_e/tbtts_e/tbtts080322am_e.htm
[4] Director of international cooperation division, China National Accreditation Services for Conformity Assessment (CNAS).

published the list of accredited testing laboratories for facemasks and other personal protective products that helped EU authorities to gain confidence in CNAS accreditation. CNAS had received more than 500 enquires asking to confirm authenticity of test reports and CNAS assigned dedicated staff to provide timely responses to all enquiries. This case study, he said, demonstrates that accreditation plays a critical role in reducing barriers to trade and facilitating cross-border trade in goods.

2.3. **Mr. Reinaldo Figueiredo**[5] (United States) presented an overview on the global acceptance of conformity assessment results and ISO/CASCO work in this respect. He noted that CASCO is a committee in ISO that develops conformity assessment standards, guides and recommendations (these are known as the ISO/CASCO toolbox). He said that regulators and the private sector, when using the ISO/CASCO toolbox, assure the market that statements of conformity in relation to products, processes or services are well grounded. He also noted that the ISO/CASCO toolbox is widely used by conformity assessment bodies and had proven to be supportive in designing conformity assessment procedures. Mr. Figueiredo specifically referred to *ISO/IEC Guide 60:2004(en) Conformity assessment — Code of good practice* which is currently being revised. He noted that CASCO has a policy for developing standards (e.g. "common elements", neutrality principles) and explained the two layers of consensus in CASCO: national (national mirror committees) and international. Based on the above, he said that CASCO as a global network can contribute to reducing technical barriers to trade.

2.4. **Ms Stacy Cho**[6] (United States) provided an overview of a new, voluntary conformity assessment program for medical devices called the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program. The aim of the ASCA, she said, is to enhance the FDA's confidence in test methods and results, promote a least burdensome approach to the development and review of medical devices and support international harmonization. It seeks to decrease the burden of individual premarket submission and ensure that patients have timely and continued access to safe, effective, and high quality medical devices. She noted that the FDA, when establishing this program, uses existing international standards whenever possible (e.g. ISO/IEC 17011, ISO/IEC 17025).

2.5. Ms Cho provided an overview of how the ASCA program works: (i) the FDA grants ASCA recognition to qualified accreditation bodies; (ii) testing laboratories who want to be part of the program obtain an assessment from an ASCA recognized accreditation body and then obtain ASCA accreditation from the FDA; (iii) medical device manufacturers select ASCA accredited testing laboratories; (iv) ASCA accredited testing laboratories conduct testing and provide relevant information to the manufacturers; (v) the manufacturers include their declaration of conformity and ASCA summary test report in their premarket submission to the FDA; and (vi) the FDA conducts a review of the submission per the ASCA guidance documents.

2.6. **Ms Elisabeth George**[7] (United States) highlighted the value of conformity assessment from the perspective of the medical device industry. She noted that Philips is an active member of many standard-developing organizations (including ISO, IEC, CTA, AAMI, NEMA, ASTM). She said that Philips embraces the use of international standards that support the company in getting the products into the market in a timely fashion. She then explained some particularities of medical device industry, and, in this context, emphasised the need to get life-saving technologies to the patients as soon as possible by removing technical barriers to trade, focusing on good regulatory practices, and leveraging standards and conformity assessment. In this respect, Phillips supports the work of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector. Regulatory misalignment impacts the time to market and potentially access to key innovations. In seeking authorization in the US and EU markets, Philips will submit the same test data and certifications, but must go through two different review processes; this increases the burden. In this respect, she called for further efforts to advance the work on an IMDRF Medical Device Single Review Program (MDSRP). In other markets like Brazil, China or Japan, conformity assessment produces were not globally aligned, and variations between regulators in terms of structure, resources and standards recognition leads to different requirements for retesting, re-certification and additional labelling. Ms George emphasized the benefits of manufacturers being able to test once, and submit

[5] Chair, International Organization for Standardization, Committee on Conformity Assessment (CASCO) (ISO).

[6] Senior Policy Analyst, Standards and Conformity Assessment Program, Center for Devices and Radiological Health, U.S. Food and Drug Administration.

[7] Head of Global Regulations & Standards, Phillips.

the same data to all jurisdictions, which supports a more rapid access to markets giving all patients globally the same care.

2.7. **Ms. Gillian Kelleher**[8] (United States) stressed the value of accreditation in the work of the Global Food Safety Initiative (GFSI). The GFSI brings together 37 retailers and manufacturers to oversee food safety standards for consumers and plays a unique role in enhancing food safety management systems around the world. The GFSI focuses on three strategic objectives: (i) benchmarking and harmonization; (ii) capability building; and (iii) public-private collaboration. She explained that the GFSI does not provide food safety certification but rather recognizes certification programs that meet the GFSI benchmarking requirements, including that certification bodies must be accredited against ISO/IEC 17065 or ISO/IEC 17021, and must be assessed by accreditation bodies that are IAF members and signatories to IAF MLA. She said that these requirements provide a proven framework of checks and balances that improves the rigor and consistency of the audit of the certification process. Accreditation plays a key role in advancing food safety around the world and builds trust and confidence among food industry stakeholders.

2.8. **Mr. Sugeng Raharjo**[9] (Indonesia) provided an overview of accreditation policy in Indonesia in supporting the acceptance of export products. Starting in the 2000s, accreditation in Indonesia began to improve product quality and facilitate trade. The National Accreditation Body of Indonesia is the only national accreditation body in Indonesia. To ensure global recognition and acceptance of conformity assessment results, it became a signatory to, among others, the IAF and ILAC. Mr Raharjo elaborated on Indonesia's timber legality verification system, implemented in 2002 in light of the illegal timber trade problem in Indonesia which had made it difficult for Indonesian wood products to access international markets. However, this tool had not been effective in assuring trading partners that Indonesian timber was not produced illegally. The situation changed only after the conclusion of the Indonesia-EU Voluntary Partnership Agreement to improve forest governance and promote trade in legal timber from Indonesia to the EU in 2014 (that became effective as of 2016). This scheme helped to enhance confidence and increase export value of Indonesian wood products. This case study, he said, demonstrates that in some cases accreditation schemes are not enough in supporting the acceptance of export products, and there is also a need for concluding mutual recognition agreements.

2.9. **Mr. Emanuele Riva**[10] (European Union) emphasized the importance of having data that demonstrates the value of accreditation to economies and societies. In this respect, the IAF launched the working group on sustainability that will be open for different stakeholders. He referred to an Italian study (June 2019–May 2020) on the impact of the quality infrastructure (QI) that demonstrated that QI: (i) provides benefits for the economy; (ii) constitutes an investment for the economy (e.g. higher productivity of certified manufacturing exporting companies); and (iii) has an impact on sustainability (e.g. less injury due to the adoption of a certified management system; million tons of CO2 equivalent saved due to certifications in the energy and environmental fields). To better understand trends in certification and sustainability, he mentioned the IAF CertSearch database of accredited certifications. He reported that the IAF was in the process of merging with the ILAC to arrive to one organization and align from a technical point of view.

2.10. **Mr. Andreas Steinhorst**[11] (European Union) discussed the role of accreditation in the EU single market for goods and international trade. He explained that the European co-operation for Accreditation (EA) is an association that comprises 49 national accreditation bodies and is recognized by the European Commission as the European accreditation infrastructure. He explained that two decades ago the European accreditation landscape had been fragmented, and, as a result, conformity assessment bodies needed to obtain several accreditations. In 2008, the European Commission reached consensus to establish a common accreditation framework. He then explained key principles of accreditation from the EU perspective: (i) accreditation is the last level of control in conformity assessment process; (ii) accreditation serves public interest; (iii) national accreditation bodies act as public authorities; (iv) accreditation is not-for-profit activity; (v) there must be no duplication in the work of conformity assessment and accreditation bodies; (vi) there must be only

[8] CEO & President Kelleher Consultants LLC.
[9] Director of Harmonization System and Accreditation, National Standardization Agency of Indonesia.
[10] Accredia Vice General Manager and IAF Chair (IAF).
[11] Executive Secretary of EA (European co-operation for Accreditation).

one national accreditation body; and (vii) accreditation bodies shall be evaluated by the EA. He also highlighted the crucial role of international standards (the ISO/CASCO toolbox) in this context.

2.11. He explained how the accreditation framework is used in free trade agreements. For example, CETA contains a TBT Chapter which refers to the CETA protocol on the mutual acceptance of the results of conformity. This protocol establishes a framework for mutual recognition of accreditation and conformity assessment bodies for the covered sectors (e.g. electronic goods, machinery, toys). This framework will allow EU companies in selected product categories to have their products tested and certified for the Canadian market in the EU, as well as Canadian companies to have their products tested and certified for the EU market in Canada.

2.12. **Mr. Mpho Phaloane**[12] (South Africa) presented South African's National Accreditation System (SANAS) and the acceptance of conformity assessment results. He said that SANAS is the sole accreditation body for the South Africa established in terms of "Accreditation for Conformity Assessment, Calibration and Good regulatory Practice Act, Act No. 19 of 2006". SANAS is internationally recognized as signatory to the ILAC/IAF/AFRAC MRAs, and a monitoring authority for the OECD GLP compliance. He underlined the common aim of the IAF and ILAC to support conformity assessment schemes which reduce risk for businesses, regulators and consumers by ensuring that accredited services can be relied upon. He said that although ILAC/IAF MRA/MLA is broadly accepted in the voluntary domain, there is still work to be done to adopt a system in terms of the regulatory domain. In this context, he referred to the TBT Committee's Indicative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment. All the listed approaches require a level of assurance of the competence of the conformity assessment bodies so that conformity assessment results can be trusted, and accreditation plays an important role in this respect. In order to overcome barriers related to differing conformity assessment procedures, WTO Members should use the existing global structures of ILAC and IAF for the mutual acceptance of conformity assessment results.

2.13. **Ms. Lana Marashdeh**[13] (Jordan) described the role of accreditation in the implementation of the Sustainable Development Goals (SDGs). Although COVID-19 slowed countries' progress in achieving the SDGs and widened the gap between developing and developed countries, accreditation still has a vital role in achieving SDGs. In particular, accreditation provides technical foundations that are critical to the functioning of developed and developing societies, helps producers to achieve greater acceptance of products, and provides consumers with a greater confidence in products. The positive impact of accreditation is clearly aligned with the SDGs pillars. She referred to the Jordanian decision to exempt accredited energy efficient products from taxes as an example of how to use accreditation for both reducing technical barriers to trade and achieving SDGs.

2.14. **Mr. Paul A. Moliski**[14] (United States) presented on accreditation from the perspective of a conformity assessment body (Intertek). Intertek strives to use internationally harmonized standards to test products once, certify them and have them accepted globally. He noted that accreditation is Intertek's licence to do business, especially for providing access to international markets. In this context, he explained that individual requirements in certain countries or regions slow business and trade and there are some processes that require duplicative accreditations. In this respect, he mentioned the need for multiple accreditations for the 6 laboratories operated by Intertek in the EU market. In particular, he noted that ILAC and IAF systems do not always recognize differences in national or regional requirements and regulations. There was a need for additional flexibility with respect to national implementation of ILAC and IAF resolutions and mandatory documents in light of these differences. Another issue he highlighted is that the relationships between the conformity assessment and accreditation bodies do not always constitute a fruitful partnership, and called for more productive collaboration with accreditation bodies.

3 DISCUSSION

3.1. The discussion was focused on the following issues: (i) how accreditation can be used to further reduce technical barriers to trade; (ii) how cooperation between accreditation systems can be

[12] Executive (Accreditation) at the South African National Accreditation System.
[13] Director of the Jordan Accreditation System (JAS-AU).
[14] Global Vice President of Accreditation, Intertek.

leveraged to avoid technical barriers to trade; and (iii) lessons learned during the COVID-19 pandemic.

3.2. With respect to the first two issues, participants emphasized the key role of the ILAC and IAF framework for recognition of conformity assessment results and overcoming technical barriers to trade. Active cooperation among national accreditation bodies of ILAC and IAF framework was vital to build mutual confidence and trust. However, some challenges with the IAF and ILAC platforms were mentioned. The growth of private conformity assessment schemes was overshadowing the established system under ILAC and IAF and created confusion. With respect to medical devices, national deviations and additional regulatory requirements limited the potential benefits of ILAC and IAF, such that in some markets a product could immediately be placed on the market, while in others, this can take two to three years. The lack of flexibility on national implementation of ILAC and IAF directives had been costly for accreditation and certification bodies in certain countries. However, it was pointed out that 90% of countries have a similar accreditation system, with one national accreditation body per country.

3.3. Participants stressed the importance of: (i) building productive relationships between accreditation bodies and local regulators; (ii) concluding mutual recognition agreements for building further confidence in conformity assessment procedures of trading partners; and (iii) stakeholders' engagement for greater collaboration among accreditation bodies.

3.4. With respect to the COVID-19 pandemic, there was discussion of how accreditation bodies in developed and developing Members pivoted to remote assessment, which was not precluded under the ISO/CASCO toolbox. COVID-19 accelerated innovations in accreditation, and led to rethinking the methods, breadth of expert participation and frequency of assessments (e.g. audits can occur more frequently with remote tools). In some cases, there was a need to change or provide interpretations of standards to provide the necessary flexibility (e.g. certain standards specify one audit per year), but such interpretations should in any event be in line with the ISO/CASCO toolbox. The potential to use remote assessment and digital tools varied across types of procedures (e.g. certification or inspection). Accreditation bodies need to establish strong relationships with regulators to help facilitate trade.

4 COMMENT BY THE MODERATOR

4.1. We heard many useful national and sector case studies on how accreditation systems can help reduce technical barriers to trade, and how cooperation between accreditation systems can help in that regard. International standards, guides and recommendations of the ISO/IEC CASCO are the foundation for accreditation and, thus, are integral for facilitating acceptance of conformity assessment results.

4.2. We talked about how accreditation facilitates mutual recognition of conformity assessment results and, therefore, has trade-facilitating effects. In this context, the IAF and ILAC are widely recognized platforms for promoting recognition and acceptance of test results through cooperation among accreditation bodies. The importance of mutual recognition agreements for building further confidence in conformity assessment procedures of trading partners was repeatedly highlighted. However, some challenges with the IAF and ILAC platforms were mentioned, such as how to handle national deviations, and the need to provide flexibility in the implementation of resolutions and in relation to mandatory documents that may not be appropriate for all countries or regions. We discussed the use of accreditation framework in FTAs. For example, CETA contains a TBT Chapter and a protocol on the mutual acceptance of the results of conformity. This protocol establishes a framework for mutual recognition of accreditation and conformity assessment bodies for the covered sectors.

4.3. Our discussion highlighted the importance of stakeholders' engagement for greater collaboration among accreditation bodies, including with regulators and the private sector. Medical devices were highlighted as a sector where accreditation holds great potential to facilitate trade and reduce barriers. One example demonstrated how regulators can trust and rely on accredited testing laboratories to perform pre-market testing of medical devices. Given the need to get lifesaving medical technologies to patients as quickly as possible, there was a suggestion for further cooperation between medical device regulators to facilitate registration procedures.

4.4. Accreditation was a tool for supporting implementation of the SDGs, and we heard an example of how it had helped to promote the use of energy efficient products. We also heard about the value of accreditation in facilitating global trade in safe food. The growth of private conformity assessment schemes was creating confusion and tended to duplicate government schemes.

4.5. We discussed the impact of the COVID-19 pandemic on the global accreditation system. In this context, accreditation has been essential for accelerating trade in medical goods. Cooperation between accreditation bodies and regulators allowed quality and safety assured personal protective equipment to move quickly across borders to fill supply gaps. Accreditation bodies worldwide turned to remote assessment to ensure continuity of their work while still ensuring rigor and confidence in product quality. The use of hybrid or remote assessment formats was expected to continue after the pandemic, although in-person visits would still be an integral component of the process.