



Committee on Technical Barriers to Trade

**PRACTICAL GUIDELINES FOR REGULATORS ON CONFORMITY ASSESSMENT
PROCEDURES: VIEWS FROM AUSTRALIA**

Submission from Australia

The following submission, dated 7 November 2019, is being circulated at the request of the delegation of Australia.

1 INTRODUCTION

1.1. Australia acknowledges the mandate provided by the Eighth Triennial Review (G/TBT/41), whereby WTO Members agreed to initiate work on developing non-prescriptive, practical guidelines to support regulators in the choice and design of appropriate conformity assessment procedures (the Guidelines). Australia acknowledges the contributions already made by other Members on this topic, including the European Union (JOB/TBT/322) and the United States (JOB/TBT/326), and welcomes views from all Members. Australia provides its thanks for this opportunity to draw on the collective experience of Australia's standards and conformance infrastructure, and respectfully makes this submission to share Australia's views on some core principles and considerations for the Guidelines, for the Committee's consideration.

2 AUSTRALIAN EXPERIENCE AND GUIDANCE

2.1. Australia's standards and conformance infrastructure (commonly also referred to as technical or quality infrastructure) is well-established, helps facilitate trade, and maintains domestic and foreign confidence in the reliability and safety of products, services and systems. As with other WTO Members, Australia's standards and conformance infrastructure supports our economy by aligning with international standards wherever appropriate, and promoting the mutual acceptance of conformity assessment data in support of a robust regulatory system. It thereby underpins Australian industry innovation and global competitiveness. Importantly, it also helps avoid and reduce technical barriers to trade, while protecting industry and community interests.

2.2. Australia's technical infrastructure includes government, metrology, standards and accreditation bodies that collaborate to provide a cohesive and effective approach to policy and regulation. The Australian Government Department of Industry, Innovation and Science (DIIS) has overarching policy responsibility for standards and conformance policy. To ensure collaboration, efficiency and innovation occurs across the technical infrastructure system, DIIS works closely with the four peak bodies that have formed the Australian Technical Infrastructure Alliance (ATIA).¹ These bodies are:

- The National Measurement Institute, Australia (NMIA) — an Australian Government body, responsible for maintaining, regulating and ensuring the international credibility of Australia's measurement system – including biological, chemical, legal, physical and trade measurement;
- Standards Australia — a membership-based, independent, not-for-profit national standards development body;

¹ For more information on the ATIA, please visit: www.atia.org.au.

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- [The National Association of Testing Authorities, Australia \(NATA\)](#) — a membership-based, independent, not-for-profit national accreditor of laboratories and testing facilities; and
 - [The Joint Accreditation System of Australia and New Zealand \(JAS-ANZ\)](#) — a bi-national, government-owned accreditor of conformity assessment bodies involved in certification and inspection.

2.3. The Australian Government and the ATIA engage in the spirit of open and transparent communication. Governance arrangements are also in place that require the technical infrastructure bodies to operate in a manner consistent with Australia's international obligations, including under the WTO Agreement on Technical Barriers to Trade (the TBT Agreement).

2.4. To facilitate trade and meet Australia's international obligations, the Australian Government has also adopted the principle that if a system, service or product has been approved under a trusted international standard, regulators should not impose additional requirements in Australia, unless it can be demonstrated that there is a good reason to do so. This means that if a standard is to be mandated by regulation, the regulation should first consider adopting an appropriate international standard. This principle has been acknowledged in Australia's Regulatory Reform Agenda and National Innovation and Science Agenda.

2.5. The Australian Government has produced a number of guidance materials that may be of interest to the Committee:

- [Australia's Standards and Conformance Infrastructure: An Essential Foundation](#)
- [Best Practice Guide to Using Standards and Risk Assessments in Policy and Regulation](#)
- [Australian Government Guide to Regulation](#)

3 OBJECTIVES, PRINCIPLES AND CRITERIA FOR THE GUIDELINES

3.1. Australia respectfully offers the following comments and ideas regarding conformity assessment for regulators, for the Committee's consideration.

3.2. As with submissions made by other WTO Members, Australia supports the Guidelines consisting of appropriate foundational (or general/baseline) principles, in addition to some more detailed principles and guidance for regulatory conformity assessment selection, design and implementation.

3.3. Australia believes the Guidelines should be non-prescriptive, in line with the Eighth Triennial Review. Australia also proposes that the Guidelines should allow sufficient flexibility for regulators and policymakers to innovate and be able to select the conformity assessment procedure/s most aligned with their particular local needs, circumstances, and policy and regulatory objectives. Australia notes that conformity assessment procedures achieve greater potential and utility when they are strongly evidence-based and take adequate account of context, while still meeting international obligations.

3.4. It will also be important to ensure that drafting and discussion of the Guidelines effectively draws on the technical expertise and lived experience of WTO Members' national quality infrastructure (NQI) organisations. This will help ensure the Guidelines are practical, fit-for-purpose, and have broad relevance for WTO Member regulators and policymakers. WTO Members have differing economies, industry bases, systems, regulatory frameworks and levels of NQI development and capability, therefore the Guidelines will not benefit from a 'one size fits all' approach.

3.5. A further consideration will be to ensure there is no unnecessary duplication with the valuable work and guidance that already exists at the national, regional and international level – for example (but not limited to) ISO/IEC guidance on conformity assessment.² The Guidelines should seek to supplement and build on this existing knowledge base, where appropriate to the WTO TBT context.

3.6. Consideration should also be given to building in a process or mechanism to discuss, review and update the Guidelines on an ongoing basis (for example, as part of each triennial review). This should be non-burdensome for Members, but keep the Guidelines current, for example in the face of significant changes in the international standards and conformance landscape – both technically and in terms of broader societal, technological and market developments. Without ongoing discussion and engagement, the Guidelines are less likely to generate the longer-term benefits anticipated by the Eighth Triennial Review.

3.7. Australia would also like to highlight the following elements that could contribute to a successful approach to conformity assessment in regulation:

- Engaging with the NQI as a fully integrated system, rather than treating each part in isolation – i.e. metrology, standards, and accreditation/conformance. This applies more broadly to best practice policy development and regulation. A responsive, coordinated, technically competent and efficient NQI is an essential support for regulators when they are selecting, developing or assuring conformity assessment processes.
- Fostering a coordinated, proactive approach to regulatory development, bringing together government, industry, the community and the NQI through engagement and consultation. It is important to liaise with the NQI early in the regulatory development process to help achieve better regulatory outcomes and performance. This can include (but should not be limited to) advisory, consultative or review (including peer review) meetings, committees, panels or similar. Such an approach to early, broad consultation can also contribute to regulatory harmonization across agencies and jurisdictions, which is an important factor for Members with a federal government structure such as Australia.
- Taking advantage of multilateral mutual recognition and acceptance arrangements (MLAs/MRAs) for quality infrastructure. For conformity assessment this includes arrangements under the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF) and the Asia Pacific Accreditation Cooperation (APAC)³. For metrology, this includes the International Committee for Weights and Measures (CIPM) and the International Organization of Legal Metrology (OIML) frameworks⁴. These arrangements, while often voluntary, can give regulators access to a reliable pool of accredited conformity assessment options from other markets. They are also part of the suite of frameworks established by the international quality infrastructure to support the reduction of technical barriers to trade.
- Enhancing transparency and good regulatory practice. The Guidelines should emphasize the principles of transparency and good regulatory practice with regards to conformity assessment procedures. For a chosen conformity assessment approach to be effective and achieve desired policy, regulatory and trade facilitation outcomes, its content and requirements need to be fully communicated to, and understood by, relevant stakeholders. This involves meaningful consultation and information sharing on new and existing regulations, providing certainty and clarity for stakeholders. It also involves developing and implementing effective and appropriate performance assessment, accountability and costing frameworks.

² Examples include ISO/IEC Guides 60 and 68, and ISO Committee on Conformity Assessment (CASCO) materials. Available at: www.iso.org/standard/37035.html; www.iso.org/standard/29363.html; www.iso.org/sites/cascoregulators/03_considerations.html. Another example is the work of Codex, including the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems – available at: www.fao.org/3/y6396e/Y6396E03.htm.

³ The ILAC MRA (<https://ilac.org/ilac-mra-and-signatories>); the IAF MLA (www.iaf.nu/articles/IAF_MLA/14); and the APAC MRA (www.apac-accreditation.org/apac-mra).

⁴ The CIPM MRA (www.bipm.org/en/cipm-mra); and the OIML Certification System (OIML-CS; www.oiml.org/en/certificates/oiml-cs/general-information).

3.8. Australia would now like to share some additional points, broadly arranged under the areas agreed for inclusion in the Guidelines under the Eighth Triennial Review.

3.1 Criteria related to risk assessment

3.9. Australia notes that as risk increases, conformity assessment becomes increasingly important, with third party oversight adding an enhanced level of confidence in a product, service or system. Risk assessment criteria should reflect the need for policymakers and regulators to build a disciplined standards and conformance framework that is firmly evidence-based, accounting for local context and desired policy and regulatory objectives. What is perceived as high risk in one market will not necessarily be seen in the same way in another market, although such differences should be for legitimate (rather than arbitrary) reasons.

3.10. Australia believes there is benefit in viewing risk in terms of general high-level themes, including in relation to the following non-exhaustive list:

- Human health or safety
- Animal or plant health or safety
- Protection of the environment
- The prevention of deceptive practices
- Market and reputational risk, for example a loss of credibility due to export quality issues
- Challenges posed by new technologies and rapid technological change – from alternative systems for credentialing, through to more effective mechanisms for assuring chain of custody and traceable evidence of conformity (although Australia notes that technological change also brings opportunities, including for collaboration on developing regulatory solutions)
- Financial risks to consumers and businesses
- Broader risks and uncertainty, fostered by the increasingly complex global environment and rapidly changing societal, geopolitical and economic trends.

3.11. Regulation cannot eliminate every risk, nor should it – rather it is about appropriately determining and managing risk in an efficient, practical manner that also facilitates trade and meets international obligations. Different policy conditions necessitate different policy and regulatory approaches. To adequately account for risk, regulators, policymakers and the NQI must work closely together to ensure that conformity assessment systems and approaches can be adaptive, responsive, and remain relevant.

3.2 Approaches to (and elements of) conformity assessment for regulators

3.12. As already noted above, Australia would like to emphasise that conformity assessment does not occur in a vacuum and is dependent on context.

3.13. First party⁵ and third party⁶ conformity assessment both have a valid place in regulatory schemes, however offer differing levels of confidence in conformance and require the appropriate regulatory and compliance frameworks in place to support their reliable use.

3.14. The type of conformity assessment procedure that should be applied in a given situation will depend on the desired policy and regulatory outcomes, the level of risk associated with a particular product, service or system, and the views of interested stakeholders. Consideration should also be given to the likely consequences that will apply if conformance is not met, or where non-conformance is not immediately evident to even the most well-informed consumer or other interested party.

⁵ For example, supplier or manufacturer self-declarations of conformity (SDOCs).

⁶ For example, accredited testing, inspection, certification or verification and validation.

3.15. The Guidelines could therefore usefully include some agreed scenarios or case studies of situations where different approaches to conformity assessment might be selected, and explain why, based on the specific circumstances involved.

3.3 Legal and administrative frameworks

3.16. Australia would like to reiterate the importance of robust, contextually-appropriate, holistic legal and administrative frameworks to support the policy and regulatory use of conformity assessment. These will vary depending on the sector, the particular risks, and desired objectives.

3.17. Such frameworks benefit from inbuilt mechanisms for the review and evaluation of conformity assessment performance (for example by aggregating market experiences), and apportioning genuine accountability across the system – providing an incentive for improvement and a greater focus on outcomes.

3.18. Pre- and post-market considerations will also be important to capture in the Guidelines. Regulators and policymakers need to consider how best to balance these to create appropriate incentives for desired market behavior, taking into account the specific product or service sector in question. While time to market for a product or service might be an important factor for one sector, this must be weighed against the level of risk involved and then paired with a commensurate approach to conformity assessment. For example, products with a longer production run can require more of a focus on the continuity of conformity and compliance over time, including via post-market surveillance arrangements.

3.19. Stakeholders also need certainty in the interpretation of standards and the application of conformity assessment procedures in regulation, along with confidence that the system will not be undermined by fraudulent practices. It would therefore be useful for the Guidelines to include methods for identifying and combatting fraudulent malpractice, with some practical, real-life examples of the where this might arise, and which market conditions foster it.

4 CONCLUSION

4.1. Australia respectfully makes this submission as a contribution to the implementation of the Eighth Triennial Review. Australia welcomes Members' comments, and looks forward to further constructive discussions on the Committee's work to develop non-prescriptive, practical guidelines to support regulators in the choice and design of conformity assessment procedures.
