

***Regulatory Structures and Trade  
Mutual Recognition of Conformity Assessment and Use of International Standards***

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**Introduction**

In a recently completed APEC report<sup>29</sup>, APEC food, electrical and electronic, and telecommunications regulators identified the following benefits to trade in mutually recognising conformity assessments undertaken in any one of their economies:

- the facilitation of trade liberalisation through mutual recognition of conformity assessments that would otherwise act as technical barriers to trade;
- reducing the costs and time for manufacturers to gain conformity assessment by reducing or eliminating the need for duplicate approval procedures;
- increasing transparency in each others regulatory and conformity assessment requirements through exchange of information;
- provision of increased domestic and international competition, productivity and innovation in goods and services, which are expected to translate in more consumer choice at lower prices;
- provision of a basis for rationalisation of domestic conformity assessment procedures;
- builds trust and mutual confidence, and broadens and deepens the economic relationships between the parties;
- provides a basis for the development of greater competence in national technical infrastructures; and
- assists in the prevention of dumping of goods.

1. In the same report the APEC regulators identified the following problems they face in committing to mutual recognition of conformity assessments:

- the need to change regulatory systems and procedures;
- lack of resources (money, time and labour) to attend meetings, negotiate and subsequently implement mutual recognition agreements (MRAs);
- lack of confidence amongst potential participants in the competence of each others technical infrastructures;
- lack of fully developed technical infrastructures;
- the sector being considered in a MRA is not economically significant to a potential MRA participant;

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Final Report of APEC CTI 07/2001 T Promoting Participation the APEC Mutual Recognition Agreements (MRAs), presented to the APEC Subcommittee on Standards and Conformance (SCSC) on 28th February 2002 in Mexico City.

- that the MRAs do not address the most significant barrier to trade e.g. tariffs or technical regulations may be the main problem, not conformity assessment procedures;
- reluctance to make the changes required to existing technical regulations and institutions to enable mutual recognition of conformity assessment;
- low levels of political and regulator commitment, or that involvement is a political position without following up on the necessary practical implementation;
- low level of policy knowledge and understanding of MRAs;
- duplication with other MRAs, e.g. development of an ASEAN MRA, bilateral MRAs and MRAs with the EU make it difficult to prioritise negotiations and technical resources;
- inability to show tangible benefits for specific economies;
- translation difficulties from English into domestic language;
- concern over liability issues if MRAs made operational and mutually recognised conformity assessment found substandard; and
- the potential impact on domestic producers.

2. Technical regulation, conformity assessment procedures, and the use of standards (whether they are national, regional or international) affect trade. As the comments from regulators above illustrate, understanding and separating out what to tackle in terms of overcoming an existing technical trade barrier, or in endeavouring to reform or design new regulatory frameworks that do not adversely affect trade, is difficult.

3. The fact that technical regulations, conformity assessment procedures and standards pose trade barriers is also well documented from a private sector perspective<sup>30</sup>.

4. One suggested approach, as elaborated in this paper, is to tackle these barriers through considering three distinct elements:

- the relevant regulatory structure, content and administration;
- the degree to which mutual recognition of conformity assessment is permissible; and
- the extent to which international standards are referenced.

5. It is also recognised that there may be other barriers to trade originating from state action that have to be addressed in resolving a specific issue. Consideration must also be given to the fact that specific trading difficulties could simply be reflective of a correctly operating market place, that does not wish to patronise specific products or services due to consumer choice preferences.

6. This paper has been developed in the context of the WTO Agreement on Technical Barrier to Trade (TBT), the APEC Subcommittee on Standards and Conformance (APEC SCSC) Guidelines for the preparation, adoption and review of technical regulations (2000), and the Final Report (2002) on Promoting Participation in APEC Mutual Recognition Agreements (MRA) (APEC CTI 07/2001 T).

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As evident in statements from the WTO, the APEC Business Advisory Council (ABAC) 2001 Report, the OECD, and the recent the Survey of New Zealand Exporters on Non Tariff Barriers to Trade (2001).

## Regulatory Structure, Content and Administration

1. With regard to trade liberalisation and regulatory structures, content and administration a number of aspects are relevant:
  - the degree to which the regulations are structured in prescriptive or performance based terms;
  - the ability for the unique social, environmental and cultural positions of a society to be reflected in the regulatory content of the specific economy; and
  - the degree to which compliance with the regulation is administered, especially to what extent the regulator has retained a monopoly for pre or post market compliance functions.

## Prescriptive and Performance Based Regulation

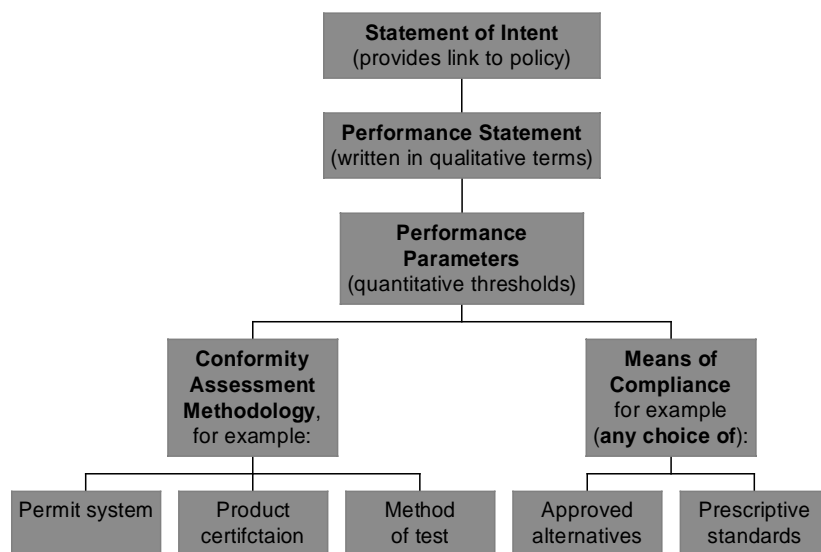
2. Article 2.8 of the TBT Agreement recognises the importance of performance based regulation, in stating that:
  - Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics
  - Prescriptive regulation generally defines a list of products, processes, and procedures required to achieve compliance. Prescriptive regulation focuses on the **means** by which the objective will be achieved rather than on whether the desired **outcome** is achieved.
  - The advantages of prescriptive regulations are that they are self-contained, precise, easily implemented, understood, followed and enforced.
  - Although easier to enforce, such regulations are often considered to be inflexible and are more likely to restrict trade and competition, inhibit innovation, and limit use of more advanced alternatives. Prescriptive approaches do not respond quickly to changing consumer preferences, technological change, changes in materials, products or systems. In effect they freeze time. More often than not the intent and purpose of the regulation becomes unknown. Like all regulations, they are difficult and slow to change.
  - In contrast, performance regulation is focused on **outcomes** rather than **inputs**. The major advantage of such an approach is that different means of compliance can be accepted provided the outcomes of the regulation are met. Thus performance-based regulation provides flexibility while achieving a specific result.
  - Flexibility in methods of compliance provides incentives for firms to look at ways to minimise the costs of complying, and so they create the right environment for innovation and technological advancement.
  - To provide a degree of certainty to market players (manufacturers, retailers and consumers) regulators can provide guidance through specifying acceptable solutions that, if followed, will be 'deemed to comply' with the regulation. These 'shake and bake' solutions can include references to voluntary international standards.
  - What is important in performance-based regimes is that they allow for alternative means of compliance. They may fail if the technical regulation is written in performance-based terms, but then there is only one means of compliance.

3. Performance based regulation requires a number of explicit statements to operate. They can be considered in the following hierarchy<sup>31</sup>:

- Statement of Intent
- Statement of Performance
- Performance parameters
- Conformity assessment methodologies
- Means of compliance

4. The following illustration shows the above hierarchy:

*The Performance Based Regulation Model*



5. Considering the extent to which regulations are prescriptive or performance based enables insights into how regulations may be reformed or structured to enable trade, while ensuring minimum performance parameters are maintained.

### **Regulatory content**

1. Having considered the desirability of a performance based regulatory structure, a regulation's content and administrative components can be considered.
2. It is important separate out these two components or characteristics, as regulators when requested to review their institutional arrangements on trade grounds will often respond in a negative or non-co-operative manner.

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<sup>31</sup> Further details on the above model can be found in a paper by the same author delivered to a APEC Good Regulatory Practice Seminar, held in Mexico City on 26th February 2002. This paper and other Good Regulatory Practice presentations can be found in the [APEC Good Regulatory Practice Database](#) hosted by the Australian Department of Industry, Tourism and Resources.

3. What is important to stress is reform of regulation to provide greater trade liberalisation does not equate to any loss of sovereignty or bypassing the right for regulation to reflect the unique social, environmental and cultural positions of specific societies.
4. Explaining this can be achieved by drawing a line between the **content** of the regulation that relates to the establishment and wording of the performance parameters, and the '**administration**' side, which covers the how compliance (or conformance) to the regulation is determined. Once regulators understand this their propensity to consider regulatory reform is enhanced.
5. This does not preclude the efforts of economies harmonising their regulation, however for the time being it is recognized this will remain a difficult proposition on a truly international scale.
6. Effectively it is acceptable to have different performance parameters or threshold enshrined in national regulation. Compliance to these thresholds remains paramount regardless where or who undertakes the compliance or conformity assessment functions.

### **Regulatory administration**

1. With reference to the administrative side of the regulatory regime in some cases changes will be necessary in regulations and institutional arrangements to allow conformity assessment by parties other than the regulator.
2. This understandably raises concerns with some existing regulators, many of whom have operated in the dual roles as sole rule setter and consent agency in the past, and in some cases are reliant on the revenue generated in pre-market conformity assessment for their operations.
3. Regulators retain a role in a reformed system by:
  - maintaining their role as the body that established the performance parameters or thresholds;
  - the granting of status to third party domestic and foreign conformity assessment bodies as being competent to determine compliance to the relevant regulations; and
  - re-establishing themselves with a focus on post-market surveillance functions rather than pre-market approvals.
4. To summarise the regulatory structure, content and administration section, trade barriers can exist through the reliance on one way of doing things. In other words the use of a prescriptive regulation that specifies one method of achieving an outcome, and the retention of a monopoly role to the regulator as the sole arbiter of whether a product or service entering an economy meets that regulation, has a high potential to act as a trade barrier in terms of costs and time delays.
5. More progressive regimes, as encouraged by international trade bodies (APEC, OECD and the WTO etc), make reference to performance based regulatory structures, where the minimum levels of performance are transparently stipulated. Manufacturers and importers are then left with the discretion to design and provide products that meet the performance outcome, rather than be limited by one specific product type.
6. This flexibility can be further enhanced by designating more than one competent conformity assessment body, and by permitting competition amongst them for conformity assessment services.

## Mutual Recognition of Conformity Assessment

1. From the basis of a performance based regulatory regime further improvements are possible in terms of reducing the costs of trade by regulators agreeing to mutually recognise the results of conformity assessment bodies deemed competent by other agencies. This is the essence of mutual recognition of conformity assessment.
2. Lack of acceptance of test data across borders and of recognition of certificates of conformity create significant barriers to trade. This can often result in multiple testing, time delays, and an overall reduction in the competitiveness of imports. One way of overcoming this problem is for economies to recognise each other's conformity assessment procedures.
3. The TBT states that economies will recognise the results of conformity assessment procedures of other members, provided they are satisfied that those procedures offer an assurance of conformity with the applicable technical regulations. The TBT Agreement does, however, recognise that an important precursor to recognition of conformity assessment procedures is confidence in each other's systems and procedures.
4. There are a range of conformity assessment options, including:
  - self declarations by manufactures that their products conform to specific technical regulations or standards,
  - market to market agreements on conformity between buyer and seller;
  - independent third party certification;
  - Government approvals, generally through a regulator or a body appointed by a regulator (these can be consents, certificates, licences, permits etc); and
  - post-market surveillance activities by regulators and consumer groups.
5. When deciding what methodology to use a regulator must give consideration to the following issues:
  - **level of risk.** In some circumstances the level of risk may require mandatory requirements for government or third party conformity assessment. This is sometimes warranted in areas where public health, safety or environmental concerns are high.
  - **the costs.** Legal requirements for conformity assessment can be both complex and expensive. A decision to impose mandatory conformity assessment requirements should only occur if the serious risk of harm justifies the cost burden of imposing regulator or third party assessment.
  - **the effects on international trade.** Consideration must be given to minimising the effects of any conformity assessment requirements on international trade. The TBT Agreement (5.1.2) states that members shall ensure:

*"Conformity Assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, inter alia that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give importing members adequate confidence that products conform with the applicable technical regulation or standard, taking into account the risks non conformity would create."*

- **the incentives on producers to comply.** In the absence of pre-market mandatory regulator or third party conformity assessment, consideration must be given to the incentives created by the post market surveillance and penalties for non-conformance, the specific demands of customers and the potential for private liability. In this regard consumer protection legislation is often used to underpin the relationship between buyer and seller;
  - **other trade related agreements.** Many economies also have bi-lateral, pluri-lateral or regional conformity assessment agreements. Examples include the APEC government-to-government MRAs and the voluntary MRA/MLAs of the voluntary accreditation agencies (more information on the latter is provided below).
  - **the likely form of conformity assessment industry in the future.** The voluntary MRA/MLAs have a considerable potential to change the nature of conformity assessment delivery options in the future. Economies should be conscious of this while making investment decisions in domestic infrastructures.
6. Consideration must also be given to the existing structures of the voluntary global conformity assessment system. Principally this refers to the groups of agencies that run accreditation activities, and the mutual recognition arrangements they currently have in place amongst themselves.
  7. These bodies operate at national (often as part of Government), regionally as cooperation's, and internationally. Examples include:

**National**

International Accreditation New Zealand, New Zealand

National Administration of Testing Authorities, Australia

Joint Accreditation System of Australia and New Zealand, Australia and New Zealand

**Regional**

Asia Pacific Laboratory Accreditation Cooperation (APLAC)

Pacific Accreditation Cooperation (PAC)

European Cooperation for Accreditation (EA)

**International**

International Laboratory Accreditation Cooperation (ILAC)

International Accreditation Forum (IAF)

8. Each of these bodies has standing mutual recognition arrangements (MRAs) or multilateral arrangements (MLAs). This means a laboratory test, management systems, or product certification by a conformity assessment body that has been accredited as competent by one member of the MRA or MLA, is acceptable to all other members of the MRA or MLA. No retesting or further certification is required.
9. These MRAs and MLAs are in the process of moving to full implementation, with a program of peer assessments and audits being carried amongst the national body members, prior to a economy gaining ascension to an arrangement. For example representative from a group of current signatories will visit and interrogate the competence of a proposed signatory. Furthermore amongst the signatories themselves there is periodic review and further peer assessment to ensure the competence of signatories remain current.

10. It is for the regulators to engage with their domestic accreditation agencies and satisfy themselves that the procedures within these voluntary arrangements for testing competence and providing conformity assessment against their native regulations is sufficiently rigorous. If so they can make reference to the voluntary agreements as a method of designating or approving conformity assessment bodies. Operating examples include testing houses and product certification bodies in Australia, certifying Australian and New Zealand products in accordance with European Directives and standards. European regulators mutually accept these certifications, as if they had been carried out in Europe.
11. This mutual recognition reduces the costs of trade substantially and allow for quicker access to markets where it is in place.

### **MRAs as a trade policy tool**

12. Before venturing into MRAs, it must be recognised they are resource intensive to negotiate and during implementation may require considerable change to existing functions and methods of conformity assessment within specific sectors. For this reason a careful analysis needs to be undertaken of the following elements:
  - what are the specific trade difficulties with in the sector;
  - what are the most appropriate tools that can be used or combined to overcome trade barriers with in a sector, such as regulatory harmonisation, bilateral or unilateral declarations of equivalence, development and adoption of international standards as the basis of compliance by regulators, and MRAs;
  - a visioning of the ‘end game’ in terms of what the trading environment will look like once full implementation is useful, from both a domestic and international perspective;
  - a proper cost benefit analysis, considering costs and benefits from both a domestic and international perspective;
  - views from stakeholders (politicians, trade officials, regulators, standards and conformance bodies, manufacturers and consumers); and
  - consideration of other trade liberalisation efforts being undertaken by other bodies related to the sector (especially other MRA efforts in different fora).
13. Only after taking into account these considerations can a reasoned decision be made that a MRA is the correct tool and that sufficient momentum is present with stakeholders to provide the necessary resources for negotiation and implementation.
14. Further considerations in MRA creation include the need to build domestic awareness and buy-in, especially by domestic regulators. Methods to achieve this can include national symposiums and training sessions with the stakeholders of a particular sector. Such training sessions should include trade officials, regulators, standards and conformance bodies (including conformity assessment bodies) and manufacturers.
15. Regulators should be directly involved in MRA negotiation and implementation at the international level, with the relative success of the APEC Electrical and Electronic Products MRA (EEMRA) and Telecommunication MRA (TelMRA) being associated with their participation in the Joint Advisory Committee and TelMRA Task Force, respectively.



16. For MRAs to function properly and certain level of technical infrastructure is required. Many respondents stated for further APEC MRA participation their economies would have to upgrade their technical infrastructures, especially to a level that enabled full participation of domestic bodies in the voluntary MRAs of APLAC, PAC and the IECEE CB scheme.
17. In this regard economies should think carefully about the resource requirements, long-term competitiveness and the possible use of established conformity assessment structures in other economies. This is especially so given the realisation that fully operating MRAs will result in the acceptance of certified products in economy A, which are produced in economy B, that may have gained conformity assessment approvals from designated conformity assessment bodies in economy C. In other words conformity assessment bodies in the future will be competing with each other to provide test reports and product certifications to manufacturers, regardless of the economy to which the exports are destined.

### **Use of International Standards**

18. At this point, we can establish that by having a performance based regulatory regime, that allows alternative means of compliance, and through MRAs compliance can be gained from any number of competent agencies, that we have substantially lessened the costs for manufacturers and importers in providing products and services to markets. However, at this point manufacturers may still need to be making several versions of a product to satisfy the performance parameters for various economies.
19. This is where international standards come into their own. Should regulators determine an international standard meets their performance parameters, then they should cite those standards as a means of compliance. As soon as this happens in several economies, the manufacturer can make one product that satisfies several markets at one time.
20. Presumably the increased economies of scale achieved may lead to reduction in costs to consumers in those markets, a more rapid time to market for new products and services, and an expansion in trade especially in those markets where previously it was considered too expensive to make specialised products for.
21. Note this does not do away with the need for each economy to specify its own sovereign performance parameters, it simply enables economies to determine that the one international standard may meet the specific thresholds, even if thresholds are cast in slightly different ways amongst economies.
22. Regulators themselves are involved in the development of appropriate international standards. International standardising bodies, such as the International Organisation for Standardisation (ISO) manage the processes where by regulators, manufacturers and consumers deliberate and create international accepted procedures for conformity assessment and international standards for products and services.

### **Summary**

23. To summarise, when considering technical barriers to trade, it is suggested consideration be given to analysing the specific problem carefully. One approach is to look first at the technical regulations that apply to the products or services of interest. There is a clear international intent that where possible such regulations should be structured in performance base terms.

24. Additionally there is a clear international understanding that while the content components of those regulations is a sovereign matter for each economy to decide, that the administrative, or conformity assessment side should permit mutual recognition of conformity assessment in cases where the body undertaking the conformity assessment is competent to do so.
25. Before undertaking negotiations with other economies on mutual recognition of conformity assessment appropriate cost/benefits need to be identified, and sufficient domestic resources need to be committed to ensure the agreements are reached and implemented. In some cases existing regulation will need to changes for regulators to designate third party conformity assessment bodies and move into a more post-market surveillance role. Regulators should have a lead role in negotiating MRAs.
26. At this point its is recognised real or perceived trade barriers can be potential reduced. Through the mutual recognition amongst regulators, and of regulators of the voluntary conformity assessment arrangements, manufacturers have a greater choice of agencies to use to gain conformity assessment for their products.
27. To further press these advantages, regulators should consider the use of international standards in terms of specifying adequate means of compliance. If this is done in several countries trade is improved, with the manufacturer needing only one conformity assessment from a conformity assessment body that has been sanctioned by several economies. Regulators should participate in international standards development.
28. The most powerful combination of regulation, conformity assessment and standards in terms of facilitating global trade and providing an innovative environment for economic development is when:
  - the regulatory structure is performance based with the ability to prove compliance using any alternative;
  - the regulator relies on post-market surveillance actions, and the use of mutual recognition arrangements of conformity assessment to accept third party conformity assessments (whether they be domestic or foreign); and
  - international standards are cited as an appropriate means of compliance with the performance parameters of domestic regulations.